SEQUOYAH COUNTY, OKLAHOMA FILED IN DISTRICT COURT

JUN 0 2 2021

# IN THE DISTRICT COURT OF SEQUOYAH COUNTY

GINA L. COX, COURT CLERK

STATE OF OKLAHOMA

Case No: CJ-21-76
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JURY TRIAL DEMANDED

PETITION

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Plaintiff, THE CHEROKEE NATION ("Plaintiff" or the "Nation"), through its Attorney General Sara Hill, brings this civil action under the common laws of the State of Oklahoma for compensatory, punitive, and other damages, and restitution, disgorgement, and any other relief allowed by law against Defendant MCKINSEY AND COMPANY, INC. ("Defendant" or "McKinsey").

#### INTRODUCTION

- I. Prescription opioids, which include both name-brand prescription opioids and their generic equivalents, are powerful pain-reducing medications. Even when used properly, these drugs can cause addiction, overdose, and death. When used to treat chronic pain, or when used for non-medical purposes, those risks are amplified. In recent years, opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of abuse. Nationwide, millions of Americans are addicted to prescription opioids, and tens of thousands die annually from opioid overdoses.
- 2. McKinsey played an integral role in creating and deepening the opioid crisis, engineering aggressive marketing campaigns for the largest opioid manufacturers, distributors, and retailers; organizing industry resistance to regulation while simultaneously advising the U.S. Food and Drug Administration ("FDA") on opioid-related rulemaking; and profiting off its investments in every business category that made money from the misery and death caused by the opioids epidemic. McKinsey's clients accounted for roughly 90% of all opioid pills sold in the United States from 2006 to 2014.
  - 3. The consultants at McKinsey are some of the best and brightest in

corporate America. McKinsey used these talents to become the ringleader of the opioid crisis—a public health crisis that flooded U.S. communities with dangerous drugs, triggering an avalanche of addiction, injury, and overdose deaths, as well as hundreds of billions of dollars in damage.

4. McKinsey advised companies at every link in the opioid "value" chain, including their manufacture, their distribution throughout the United States and, finally, their sale to consumers. But McKinsey's influence went still further. McKinsey, on its own account and through affiliations to private equity funds, made major investments in all aspects of the opioid trade, from drug manufacturers to addiction treatment facilities. In sum, McKinsey designed and implemented aggressive marketing strategies, helped dilute and delay effective governmental regulation, and reaped billions of dollars from the human misery it helped create.

#### PARTIES

#### I. PLAINTIFF

- 5. The Cherokee Nation is a federally recognized sovereign American Indian nation. It has approximately 392,000 citizens and is the largest tribe in the United States. It is governed by the Cherokee Nation Constitution and the laws of the Cherokee Nation. The Nation exercises inherent governmental authority within its reservation.
- 6. Most of the citizens of the Cherokee Nation live in a reservation spanning a fourteen-county area in northeastern Oklahoma ("Cherokee Reservation"). The Nation's headquarters are in Tahlequah, Oklahoma.

- 7. The Nation has exercised the authority granted under the Indian Self-Determination and Educational Assistance Act of 1975 to administer health programs that were previously managed by the Indian Health Service. Pursuant to that authority, the Nation operates the Cherokee Nation Health Services ("CNHS") which is the largest tribally operated health care system in the United States. It has an annual budget that exceeds \$300 million. In the clinical setting, CNHS serves over 100,000 patients through eleven health care facilities.
- 8. Cherokee Nation Attorney General Sara Hill brings this action pursuant to Article VII, Section 13 of the Cherokee Nation Constitution, Section 13 of the Cherokee Nation Constitution, and Title 51, Chapter 4 §§ 101, et seq., of the Cherokee Nation Code.
- 9. The Nation, through General Hill, also brings this action in the exercise of its statutory and common law powers on behalf of the Nation in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of the citizens of the Nation. Specifically, General Hill brings this action to stop the opioid epidemic within the Nation and to recover damages and seek other redress from harm caused by McKinsey's role in the improper marketing, sales, distribution, dispensing, and reporting practices related to prescription opioids. McKinsey's actions have caused and continue to cause a crisis that threatens the health, safety, and welfare of the citizens of the Cherokee Nation.

#### II. DEFENDANT

10. Defendant McKinsey and Company, Inc. is a corporation organized under

the laws of the state of New York. McKinsey's principal place of business is located at 711 Third Avenue, New York, NY 10017.

11. McKinsey is one of the world's largest consulting companies. Its partners work worldwide for corporations and governments across diverse industries, including Purdue and other opioids manufacturers.

## JURISDICTION AND VENUE

- 12. This Court has jurisdiction over McKinsey because McKinsey conducts business in and throughout Oklahoma and it has deliberately engaged in significant acts and omissions that have injured the Cherokee Nation and its citizens. The Cherokee Nation's claims arise out of those activities.
- 13. In addition, this Court has personal jurisdiction over McKinsey through the actions of its co-conspirators in furtherance of the conspiracy, each of which has substantial contacts and business dealings throughout the Cherokee Nation and Oklahoma by virtue of their marketing, sales, manufacturing, and distribution of prescription opioids within the Cherokee Nation territorial and political jurisdiction.
- Venue is proper under 12 Okla. Stat. Ann. § 137 because McKinsey is a nonresident and foreign corporation.

#### FACTUAL BACKGROUND

# I. MCKINSEY WAS AT THE CENTER OF THE OPIOID CRISIS

15. McKinsey's role in fueling the opioid epidemic is far more extensive than is generally appreciated, with the firm arguably doing more to boost consumption of the

deadly drugs than any other single corporation in the United States. Over the past decades, the firm worked for many of the largest opioid manufacturers, distributors, retailers, and investors. During the same period, it also performed several projects for the very division at the FDA responsible for overseeing opioid sales. The FDA's lax regulation was favorable to drugmakers in several key respects.

# A. McKinsey Worked for All of the Major Opioid Manufacturers

16. McKinsey has numerous clients that manufacture opioids. It has done extensive work for Purdue Pharma and Johnson & Johnson. It has also worked for Endo International, Mallinckrodt, Teva, Actavis and Abbott Labs. These manufacturers constituted most of the market. The federal Drug Enforcement Administration ("DEA") has published data indicating that just four of McKinsey's clients—Purdue, Endo/Par, Mallinckrodt, and Actavis—accounted for nearly 90% of all opioid pills sold in the United States from 2006 to 2014.

# 1. McKinsey and Purdue Pharma

- McKinsey's work with Purdue Pharma, which was extensive and is welldocumented, is discussed in detail below.
- 18. Purdue Pharma L.P. is a limited partnership incorporated in the state of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut; the Purdue Frederick Company Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut; and Purdue Pharma Manufacturing Inc. is a New York corporation with its principal place of business in Stamford, Connecticut (collectively,

"Purdue").

19. At all relevant times, Purdue has manufactured, marketed, distributed, and sold and continues to manufacture, market, distribute, and sell prescription opioids, including OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER to distributors, pharmacies, and physicians with locations in the Cherokee Nation.

## 2. McKinsey and Mallinckrodt

- 20. Mallinckrodt was one of McKinsey's leading clients in the opioid industry.
  The firm worked for the Irish American drugmaker during much of the 2010s.
- 21. Mallinckrodt primarily sells generic drugs, including oxycodone and hydrocodone, two of the most popular opioids on the market. Mallinckrodt's U.S. headquarters are in St. Louis, and it markets opioids through a subsidiary called SpecGx LLC.
- 22. Mallinckrodt is far less known than Purdue Pharma but, at times, it has played an even more significant role in fueling the opioid crisis. For example, between 2006 and 2014, Mallinckrodt produced more opioid pills than any other manufacturer operating in the United States, according to an analysis of DEA records by the Washington Post. The 36 billion pills manufactured by Mallinckrodt during that period accounted for 35.7% of the total market. The DEA described Mallinckrodt as the "kingpin of the drug cartel."
  - 23. Several jurisdictions whose residents have suffered from the opioid

epidemic have filed lawsuits against Mallinckrodt. Several opioid-related lawsuits against the drugmaker are ongoing.

- 24. During much of the period that Mallinckrodt was producing billions of opioid pills, McKinsey worked with the drugmaker. Accounting records submitted in connection with opioid litigation show that Mallinckrodt made more than 70 payments, worth more than \$30 million, to McKinsey from 2013 to 2017. In 2000, 2001, and 2008, Mallinckrodt made at least five additional payments to McKinsey worth a total of \$3 million. Most of those payments went to McKinsey's office in Philadelphia and several others were sent to the firm's Dusseldorf, Germany, offices.
- 25. There is some evidence that McKinsey's consulting work for Mallinckrodt concerned sales of its opioid products. Documents related to McKinsey's February 2021 settlement with state attorneys general indicate that the firm helped Mallinckrodt on its opioid sales. In addition, the timing of the payments included in the accounting records covers the same period in which McKinsey increased its work for clients in the sector.
- 26. There are additional indications of the years-long relationship between Mallinckrodt and McKinsey. The drugmaker began as a subsidiary of Tyco International, a conglomerate where several former McKinsey employees held to positions. In 2006, McKinsey led a reorganization in which Mallinckrodt and other pharma companies held by Tyco were spun off into a company named Covidien.
- 27. Covidien said in 2011 that it would take Mallinckrodt public, a process that was completed with the drugmaker's IPO in 2013. At least four executives from Tyco and Covidien became special advisers to McKinsey's M&A and pharmaceutical teams

around the time of the IPO.

## 3. McKinsey and Actavis

- 28. The McKinsey clients that produced opioids included Actavis Generics, a specialist in off-brand medicines that manufactured oxycodone and hydrocodone. The New Jersey-based company produced more than 32 billion pills from 2006 to 2014, accounting for 32% of the total national market, according to DEA records. Actavis dramatically increased its opioid production during that period: its output of oxycodone doubled, and its production of hydrocodone increased by 50%.
- 29. Actavis plc is a public limited company incorporated in Ireland with a principal place of business in Dublin, Ireland. Watson Laboratories, Inc., which is a Nevada corporation with its principal place of business in Corona, California, is a wholly owned subsidiary of Allergan plc(f/k/a Actavis, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.
- 30. Allergan plc's corporate history involves several different parent and subsidiary companies operating under different names. Watson Pharmaceuticals acquired Actavis, Inc. in October 2012; that combined company changed its name to Actavis, Inc. in January 2013, then to Actavis plc in October 2013. Actavis plc acquired Allergan plc in March 2015; that combined company then changed its name to Allergan plc.
  - 31. Each entity in that line of succession is a defendant that Allergan plc owns and

uses to market and sell its drugs in the United States. Allergan plc exercises control over those marketing and sales efforts. Profits from the sale of Allergan and Actavis products ultimately flow to Allergan plc. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to herein as "Actavis.")

- 32. Actavis markets and sells opioids throughout the United States and within the Cherokee Nation. Its most sold branded product is Kadian. Kadian is a Schedule II opioid that contains extended-release morphine sulfate, first approved in 1996 for patients hoping to manage severe pain. Actavis acquired the rights to Kadian in 2008 from King Pharmaceuticals, Inc. and began marketing Kadian in 2009. Actavis also markets and sells Norco (generic Kadian), as well as generic versions of Duragesic and Opana.
- 33. As described above, several different parent companies have owned Actavis over the past two decades. The company's production of opioids has exposed those parent companies to increased legal liability.
- 34. Allergan, which merged with Actavis in 2014, has been targeted by opioid litigation from several states and municipalities. That legal exposure has prompted speculation that Allergan could dissolve, rather than pay the penalties that may result from that litigation. Teva Pharmaceuticals, which is discussed in greater detail below, acquired Actavis in 2016. Teva has also been the target of a multitude of lawsuits.

  Ownership of Actavis has added to the legal jeopardy faced by both Allergan and Teva.
- 35. In the early 2010s, McKinsey worked on a significant Actavis merger, helping the company increase its share of the generic drug market. Actavis was acquired

by Watson Laboratories Inc., another manufacturer of generic drugs, in 2012. Media reports and corporate documents indicate that McKinsey helped Watson negotiate the deal. The firm also helped to oversee Watson's integration with Actavis. Watson hired a McKinsey consultant named Marc Lehnen to manage the integration shortly after the sale. Lehnen reported directly to the chairman of the board. The merged company retained the name Actavis after the transaction was completed.

- 36. There are many overlaps in personnel that indicate McKinsey's relationship with Actavis. In 2010, a partner in McKinsey's pharmaceutical practice named Enrico Vanni became an Actavis director. Chris Coughlin, a former Tyco CFO who became an Actavis board member in 2014, also worked for McKinsey as an advisor.
- 37. Over the same period, Actavis worked with Valeant Pharmaceutical on several drugs. McKinsey played a significant role in guiding Valeant's corporate strategy during this period.

## 4. McKinsey and Teva/Cephalon

- 38. McKinsey's involvement in the opioid industry includes its work for Teva

  Pharmaceuticals, which is the largest manufacturer of generic drugs in the world.
- 39. Teva's involvement in the U.S. opioid market stretches back to at least 2004, when its generic version of OxyContin was approved by regulators. Teva provided just under 1% of the opioid pills that were manufactured in the United States from 2006 to 2014. Teva's market share increased significantly following two major acquisitions: its 2011 purchase of Cephalon, the manufacturer of a lollipop containing fentanyl, and its

purchase of Actavis, the second-largest U.S. producer of opioids, in 2016.

- 40. Cephalon, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. acquired Cephalon, Inc. in 2011. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), a corporation organized under the laws of Delaware with its principal place of business in Pennsylvania, is a wholly owned subsidiary of Teva Ltd. Teva USA acquired Cephalon, Inc. in October 2011.
- 41. Teva USA and Cephalon, Inc. work closely with one another to market and sell Cephalon, Inc. products in the United States. Since the acquisition of Cephalon, Inc. by Teva Ltd. in October 2011, Teva USA has conducted all sales and marketing activities of Teva Ltd. for Cephalon, Inc. in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon, Inc. branded products through its "specialty medicines" division. Teva Ltd.'s financial reports list Cephalon, Inc.'s and Teva USA's sales as its own, and its year-end report for 2012—the year immediately following the Cephalon, Inc. acquisition—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through such interrelated operations, Teva Ltd. operates in Oklahoma and the rest of the United States through its subsidiaries Cephalon, Inc. and Teva USA.
- 42. The FDA-approved prescribing information and medication guide—which is distributed with Cephalon, Inc. opioids that are marketed and sold in Oklahoma, including in the 14 counties comprising the Tribal Jurisdiction Statistical Area

("TJSA")—discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

- 43. Cephalon manufactures, promotes, sells, and distributes opioids, including generic versions of OxyContin as well as Fentora and Actiq—both Schedule II opioids indicated for the management of breakthrough pain in cancer patients—in the United States and in the TJSA. Fentora is a fentanyl tablet that is placed inside an individual's mouth in a manner similar to chewing tobacco and then allowed to dissolve. Actiq is a fentanyl citrate lozenge similar to a lollipop. Actiq was granted restricted marketing approval by the FDA in 1998 and was to be promoted only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."
- 44. Teva has been the target of a multitude of opioid-related lawsuits.

  McKinsey worked for Teva in 2012. The drugmaker hired the firm to oversee a management reform known as Project Spring. Industry reports indicate that the reforms undertaken as part of Project Spring included a greater focus on routine corporate acquisitions. McKinsey's pharmaceutical practice has frequently advocated for such regular acquisitions.
- 45. McKinsey continued to work for Teva after Project Spring was completed. In 2016, a Teva manager corresponded by email with McKinsey consultants about the drugmaker's Medicare payment programs. Those exchanges were included in documents released by the U.S. Attorney's office in Massachusetts, which was investigating Teva for fraud. McKinsey does not appear to have been a target of the Massachusetts

investigation, but the correspondence suggests that the firm consulted with Teva about ways to ensure that patients could use Medicare to obtain drugs that it manufactured.

46. Kare Schultz, who became Teva's CEO in 2017, spent the early part of his career at McKinsey. Schultz has also held leadership roles at several other drug companies that hired McKinsey. Several other McKinsey alumni also serve in key positions at Teva. For example, after a long career at McKinsey, Roger Abravanel joined the Teva board in 2007, remaining in that position for a decade.

# 5. McKinsey and Endo International/Par Pharmaceutical

- 47. Another McKinsey client that played a central role in the opioid crisis is Endo International. Endo International plc has two principal places of business: one in Dublin, Ireland and the other in Malvern, Pennsylvania.
- 48. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.
- 49. Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceuticals Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par Pharmaceutical") were acquired by

Endo International plc in September 2015 and serve as the operating companies of Endo International plc. (Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Endo International plc, and Par Pharmaceutical are collectively referred herein to as "Endo.")

- 50. The opioids manufactured by Endo include Percocet and Opana, as well as oxycodone and morphine. Endo's purchase of Par Pharmaceutical, one of the largest makers of generic opioids, in 2015 gave it a significant role in opioid epidemic. Par made 18 billion opioid pills from 2006 through 2014, accounting for 17.6% of the total market. Only Mallinckrodt and Actavis produced more pills during that period.
- 51. Endo's best-selling opioid for many years was Opana ER, an extended-release painkiller. Following reports that drug users were crushing Opana ER and then snorting or injecting it, in order to get the full effect all at once, rather than over time, Endo released a reformulated version in 2012. While the new version was intended to make such abuse more difficult, some users continued to crush the Endo pills and inject the opioid powder, leading to outbreaks of diseases such as HIV and hepatitis C among people who had shared needles. In 2017, the FDA asked Endo to pull Opana ER. The agency said it had never before sought to remove an opioid pain medicine from the market because of concerns about abuse. Endo withdrew Opana ER and also said it would voluntarily stop promoting its opioid medications and stop research and development on new opioids.
- 52. In the \$600 million settlement that McKinsey reached with 49 states in February 2021, Endo is listed among McKinsey's opioid clients. McKinsey designed and implemented marketing programs for Endo, "increasing the sale and use of opioids,"

according to documents filed in the case.

- 53. McKinsey veterans have served in the top levels of Endo management. In 2013, the drugmaker tapped a former McKinsey principal named Rajiv De Silva as its new CEO. De Silva had previously been an executive at another pharmaceutical company, Valeant, which often turned to McKinsey for advice on acquisitions. After he joined Endo, De Silva launched a series of acquisitions of his own, apparently relying on a version of the strategy that McKinsey had helped forge at Valeant.
- 54. Endo's purchase of DAVA Pharmaceuticals, a generic drug specialist, in 2014 was one of the first deals that De Silva pursued at the drugmaker. Court filings in a securities case show that Endo hired McKinsey to provide "the pre-acquisition valuation of the DAVA acquisition." McKinsey's early work on mergers often evolves into a much more expansive role for the firm, including the provision of strategic advice and help with the integration of the merging companies.
- 55. In 2015, Endo acquired Par Pharmaceuticals for \$8 billion. Before that deal, Endo had been providing less than one half of 1% of the supply of opioid pills in the country. The acquisition of Par made Endo the third largest opioid producer in the United States. De Silva's use of McKinsey during his 2014 acquisition, as well as the mergers he pursued during his time at Valeant, suggests that he may have again sought assistance from the firm for the Par deal.
- 56. Personnel overlaps also suggest that McKinsey may have been involved with Endo's acquisition of Par. At the time of the deal, Par was owned by TPG, a private equity firm with \$85 billion in assets. TPG's pharmaceutical and health care team is

made up largely of former McKinsey consultants who were closely engaged with Par.

57. A McKinsey publication in August 2015 noted that TPG had collected a sevenfold return on the Par sale. At the conclusion of deal, TPG retained a stake in Endo worth more than \$1.5 billion, making the fund the largest shareholder in the drug company. TPG appears to have held a significant stake in Endo until February 2020.

## 6. McKinsey and Abbott Laboratories

- 58. McKinsey has also worked for Abbott Laboratories, which worked with Purdue Pharma in the late 1990s, as Purdue sought to expand its opioid sales.
- 59. The FDA approved Purdue's OxyContin painkiller in 1995. The following year, the drugmaker hired Abbott. At the time, Abbott, based outside Chicago, was larger than Purdue. Tapping Abbott to help sell its opioid to doctors, hospitals, and others helped Purdue expand its reach across the country.
- 60. Under their joint sales promotion program, Abbott provided 300 sales representatives a year to promote OxyContin. The additional salespeople doubled Purdue's sales team in the initial years of the partnership, which remained in place for seven years. The program is similar in many respects to the advice that McKinsey would give Purdue a decade later about how to "turbocharge" sales of its opioid painkillers. With Abbott's help, Purdue increased sales of OxyContin from \$49 million in 1996 to \$1.6 billion in 2002. Over the same period, the country suffered its first wave of overdose deaths attributed to opioids. Public health officials have attributed the mounting deaths to the increased use of prescription opioids such as OxyContin.

- 61. Abbott used aggressive tactics to market OxyContin. Internal company documents obtained by Stat show that "the sales team referred to the marketing of the drug as a 'crusade,' and their boss called himself the 'King of Pain.'" Top salespeople were awarded prizes of \$20,000.
- 62. Under the terms of their partnership, Purdue paid Abbott nearly \$500 million. Abbott noted in its 2003 annual report that it was facing 306 lawsuits related to its OxyContin work. To date, the company appears to have avoided significant legal exposure for its early opioid work because Purdue indemnified Abbott as part of their arrangement.
- 63. Miles D. White, a former McKinsey partner, took over as CEO of Abbott in 1999. Abbott announced a \$6.9 billion acquisition of Knoll, a German drugmaker, in 2000. The deal was important one for Abbott, leading the company to develop and launch Humira, which is now the top selling drug in the world.
- 64. White engaged McKinsey for help with the Knoll deal. Court documents show that Abbott hired the firm in late 2000 or early 2001 to manage the integration with Knoll. This timeline means McKinsey was working with Abbott during the period that the drug company was using aggressive sales tactics to increase sales of OxyContin.
- 65. Additional evidence demonstrates McKinsey's broad role in providing advice to Abbott and its CEO while Abbott was encouraging doctors to prescribe more OxyContin. The former managing partner of McKinsey's Chicago office, Richard Ashley, became a top executive at Abbott in 2004. While at McKinsey, Ashley "was an adviser to Abbott on various corporate matters, including strategy and governance," an

indication that the firm's work included more than its advice on the merger with Knoll.

- 66. Taken together, the evidence suggests that McKinsey helped to craft Abbott's strategy at a critical time, as the drug company was working to broaden its position in the opioid sector.
- 67. McKinsey and Abbott appear to have continued to work together for several years after the Knoll acquisition. In 2013, McKinsey featured an interview with White, Abbott's CEO, in one of the firm's publications. Such friendly coverage of an executive is often an indication that the firm is working for a company. According to corporate records filed by Mylan, McKinsey advised that company on its acquisition of Abbott's generics arm in 2014. Abbott is also listed among the current clients of McKinsey's design subsidiary, Lunar.
- Abbott, another indication of the firm's influence with the company. White became
  Abbott's executive chairman in 2020, when he stepped down as chairman and CEO. In
  addition to Ashley, several other top Abbott executives previously worked for McKinsey.
  They include Katherine Doyle, an Abbott board member who joined the company in 2011
  from McKinsey, and John Schilling, joined Abbott in 2008 from McKinsey. Schilling
  managed sales and marketing at Abbott, the same work that Abbott did for McKinsey's
  client, Purdue.

# 7. McKinsey and Johnson & Johnson

69. McKinsey also worked for Johnson & Johnson, an American pharmaceutical and medical device company headquartered in New Brunswick, New Jersey, in designing

aggressive marketing programs to push opioid sales.

70. In the early 2000s, McKinsey encouraged Johnson & Johnson to target high-risk populations aggressively. In one presentation from 2002, for instance, the firm advised Johnson & Johnson to "[t]arget high abuse-risk patients (e.g., males under 40)." The firm also suggested that Johnson & Johnson reach out to doctors specializing in treating elderly patients with back pain and expanding some of its stronger painkillers beyond use in cancer patients.

# B. McKinsey Worked for All of the Major Opioid Distributors

McKinsey also worked for the three major drug distributors: McKesson,
 Amerisource Bergen, and Cardinal Health.

## 1. McKinsey and McKesson

- 72. McKinsey's client roster includes McKesson, the largest distributor of opioids in the U.S. The company, based in Irving, Texas, accounts for one-third of all pharmaceuticals used in North America. McKesson serves more than half of U.S. hospitals and one-fifth of American physicians.
- 73. McKesson distributed 19 billion oxycodone and hydrocodone pills between 2006 and 2014, more than any other distributor. The pills provided by McKesson made up 18.9% of the pills shipped in the country during that period. During a December 2017 episode of 60 Minutes, David Schiller, the DEA assistant special agent in charge of the lead field team for the agency's investigation of McKesson, said the company is "at the forefront" of the opioid epidemic.

- 74. McKinsey's relationship with McKesson stretches back to at least 2008.

  That year, the firm prepared a proprietary report for McKesson about the process of authorizing medication requests with insurance companies, a critical issue for the opioid industry. If McKinsey's report resulted in a streamlined approval process for opioid prescriptions, both McKesson and the broader opioid market would have benefited.
- 75. McKinsey appears to have consulted for McKesson on a wide range of matters for at least a decade following the 2008 report. In 2013, the firm worked with a McKesson unit based in the United Kingdom that provides the National Health Service with IT services. In a 2017 post on an online message board, a person described as a McKesson employee said the company had brought in McKinsey to assist with a reorganization of the general counsel's office. McKesson's principal legal exposure for several years has been its opioid liability.
- 76. Several video and print interviews conducted between 2006 and 2012 by McKinsey Quarterly with McKesson's former CEO, John Hammergren, further indicated a close relationship between the firm and the drug distributor. McKinsey has a long pattern of promoting its clients and their executives in the Quarterly and other company publications. The McKinsey interview with Hammergren suggests that McKesson may have hired the firm as early as 2006, shortly after McKinsey's first known work for Purdue Pharma.
- 77. There is additional evidence that McKesson remains an active McKinsey client. A McKesson executive recently participated in a McKinsey leadership program that appears to be exclusively for employees of companies that have retained the

consulting firm.

- Program, part of the "McKinsey Academy," as a service the firm provides to its clients. The Black Executive Leadership Program is an offshoot of the firm's Executive Leadership Program, whose participants "are nominated by their organization's leaders in conjunction with their McKinsey client service team." James Frison, who is both McKesson's senior director for social impact and president of the McKesson Foundation, has been listed as an executive sponsor of McKinsey's Black Executive Leadership Program since December 2020.
- 79. Many high-ranking executives have also jumped between McKesson and McKinsey. At least three McKesson employees have left the drug distributer in recent years to join McKinsey. They include Neema Uthappa, who was the global director of automation, AI, and engineering at McKesson from 2017 to 2021. Uthappa was recently named McKinsey's head of data and analytics engineering.
- 80. There have also been significant personnel flows in the opposite direction.

  The roster of current and former McKesson executives includes at least 11 people who worked at McKinsey earlier in their careers. This pattern of McKinsey consultants going on to take senior positions at McKesson dates back to the 1970s.
- 81. Many of the former McKinsey employees who moved on to McKesson worked as consultants for the distributor before they became full-time employees at the company. One such example is Marc Owen, who was a member of McKesson's executive committee from 2001 to 2017. Prior to joining McKesson, he was a senior

partner at McKinsey with a focus and pharma and health care, with McKesson among his clients. Similarly, McKesson Vice President Ramesh Srînivasan joined the distributor in 2013, after seven years at McKinsey. Nathan Gosse, who occupied a post as vice president in McKesson from 2011 to 2020, also joined immediately from McKinsey, having worked for the consulting firm from 2008 to 2011. Other top McKesson executives who previously worked at McKinsey include Erin Young, the chief marketing and merchandising officer of McKesson Canada, and Jose Queijo, a senior director of strategy at McKesson since April 2020.

#### 2. McKinsey and AmerisourceBergen

- 82. McKinsey also performed engagements for AmerisourceBergen, the second largest pharmaceutical distributor in the United States. The distributor, based in Chesterbrook, Pennsylvania, accounted for 13.2% of all oxycodone and hydrocodone pills shipped in the United States from 2006 to 2014, more than 13 billion in all.
- 83. AmerisourceBergen appears to have a longstanding professional relationship with McKinsey. In March 2018, for instance, AmerisourceBergen tapped McKinsey to consult on, among other topics, the distributor's outreach to drug manufacturers.
- 84. A filing submitted as part of a lawsuit against the big three distributors by Huntington, West Virginia, and surrounding Cabell County, is indicative of McKinsey's work for AmerisourceBergen. The expert witness report refers to a materials AmerisourceBergen provided to McKinsey as part of its engagement, including marketing and promotional literature, price lists for its advertising campaigns, and details of past

strategies for targeting patients and providers. Such issues were typical of McKinsey's consulting work for companies in the opioid sphere.

For instance, Leslie Donato, the distributor's chief strategy officer and executive vice president spent nearly 15 years at McKinsey in the 1990s and 2000s.

AmerisourceBergen's chief information officer, Mark Spykerman, joined the distributor in 2012 after a five-year stint at McKinsey. Sara Fernandez, who headed an AmerisourceBergen consulting division from 2008 to 2018, came to the distributor after two years at McKinsey. And Eric McCafferty, AmerisourceBergen's recently named vice president for strategy and corporate development, was a McKinsey consultant from 2001 to 2011.

# 3. McKinsey and Cardinal Health

- 86. McKinsey has long worked for Cardinal Health, the third member of the big three distributors. Headquartered in Dublin, Ohio, Cardinal Health operates the "largest generic sourcing entity in the U.S." in partnership with CVS Caremark. According to DEA data, the distributor was responsible for shipping the second largest quantity of oxycodone and hydrocodone in the U.S. from 2006 to 2014—15 billion pills total.
- 87. At least one Cardinal Health executive recently completed a McKinsey leadership program that the firm offers exclusively to clients, indicating that Cardinal Health is a client. Stephanie Revish, the distributor's vice president for finance transformation, completed McKinsey's Black Executive Leadership Program in January

2021.

- 88. Two additional Cardinal Health vice presidents have also completed the same program: Angela Thomas, a 26-year veteran of the company, and Rick Bright, who joined Cardinal Health in 2018 after six years at AmerisourceBergen.
- 89. Cardinal Health has participated in several McKinsey initiatives in which it typically works with client firms. These include a 2018 study of women in corporate American, titled "Women in the Workplace." In 2009, Karry Clark, who then served as chairman and CEO of Cardinal Health, was among 14 interviewees in a McKinsey Quarterly article about their response to the Great Recession. The executives featured in these articles often work for McKinsey clients.
- 90. On at least two prior occasions, Cardinal Health executives acknowledged hiring McKinsey. In a 2010 interview, Jeff Henderson, then the distributor's CEO, alluded to the firm's work on strategic issues like cost-cutting and IT: "If we engage Deloitte or McKinsey, we designate a very senior executive as its sponsor, to understand and monitor any and all projects being done by that firm." Four years earlier, former CEO David Schlotterbeck said the company had "been working with McKinsey & Co. on developing large-scale strategies for Cardinal Health on a global basis," in response to a question about the firm's operations in Europe.
- 91. As with its big three competitors, Cardinal Health has also hired executives from McKinsey on repeated occasions. Nancy Killefer spent 21 years at McKinsey—and reportedly founded the firm's public-sector practice, which has worked extensively with the FDA—before being named to Cardinal Health's board of directors in 2015. Former

McKinsey pharma partner Michele Holcomb has been executive vice president and chief strategy and business development officer at Cardinal Health since 2017. Other McKinsey alumni who later moved onto Cardinal Health include Rudy Poussot, who served as vice president for corporate strategy at Cardinal Health between 2010 and 2017, and Nicolette Jang Turner, a director and vice president at Cardinal Health from 2016 to 2020.

#### C. McKinsey Worked for Major Retailers Who Sold Opioids

92. McKinsey has performed multiple engagements for two of the largest retail vendors of opioid drugs—CVS and Walmart. The two pharmacy chains have hired McKinsey to deal with a host of different strategic issues, likely including their opioid sales. Other McKinsey clients in the opioid sphere have launched initiatives with CVS and Walmart, a likely sign of McKinsey's coordination.

#### McKinsey and CVS

- 93. McKinsey has worked extensively for CVS over the past decade. CVS Pharmacy, Inc. is a Rhode Island business entity with its principal place of business in Rhode Island.

  CVS Health Corporation (together with CVS Pharmacy, Inc., "CVS") is a Delaware business entity with its principal place of business in Rhode Island.
- 94. CVS is authorized to conduct business in Oklahoma. At all relevant times, CVS has sold and continues to sell prescription opioids at locations in Oklahoma that serve citizens of the Nation, including near hospitals, clinics, and other health care facilities serving patients of the Nation's health care system.

- 95. CVS operates nearly 10,000 retail locations across the country. The chain has been among the country's top sources of opioids, providing 7.7 billion pills, or 7.6% of the market, from 2006 to 2014. The chain ranks second only to Walgreens among pharmacy chains in the provision of opioids.
- 96. CVS has already been sanctioned for its lax oversight of opioids. The company reached a \$22 million settlement with the Department of Justice in May 2015 following charges that the chain and its wholesale supplier, Cardinal Health, knew that large orders of oxycodone were being shipped to two of its Florida locations but did nothing to investigate the suspicious sales.
- 97. According to its most recent annual report, CVS is a defendant in hundreds of opioid-related cases, including cases brought by several state attorneys general. CVS also said that, in January 2020, it was served with an administrative subpoena seeking "documents relating to practices with respect to opioids...."
- 98. CVS is reportedly among McKinsey's biggest clients. CVS is listed among the users of Periscope, a platform built by McKinsey that provides retailers with data and analytics tools. CVS is also mentioned regularly in McKinsey publications, which often indicates an ongoing client relationship.
- 99. There are several indications that a McKinsey managing partner named Rodney Zemmel was among the firm's executives who worked with CVS. Zemmel co-authored a 2018 book, Go Long: Why Long-Term Thinking is Your Best Short-Term Strategy. The book praised CVS CEO Larry Merlo, pointing to him as an example of a CEO who adopted a long-term strategic approach.

100. In a 2018 interview, Zemmel continued his praise of Merlo:

When [Merlo] and his team made the decision to stop selling cigarettes, not only was the decision extremely well syndicated, extremely well thought through, extremely well managed from all the operational details. But also, they did it at a time when the company was performing well.

- 101. Zemmel, who was reportedly among the candidates to succeed Kevin Sneader as McKinsey's global managing partner, previously led the firm's health care practice and worked with several pharmaceutical clients. Today, Zemmel leads McKinsey Digital, a division of the firm that focuses on big data and analytics—which is likely connected to CVS's use of McKinsey's big data platform Periscope.
- 102. Zemmel has also written articles with several McKinsey consultants whose work at the firm included advising opioid manufacturers as well as the FDA. In 2010, he co-authored a McKinsey article that examined drug failure rates in clinical trials. His co-authors on the article, entitled "Anatomy of Attrition," were Maria Gordian and Navjot Singh. As noted below, Gordian was a key adviser to Purdue Pharma and helped the manufacturer implement its risk evaluation and mitigation strategies and approval strategies for extended-release opioids. During the same period, Singh appears to have represented McKinsey in several of its engagements with the FDA.
- 103. As shown by LinkedIn profiles, CVS and McKinsey are also connected by a personnel pipeline. McKinsey associate Diya Sikka joined the consultancy in 2017 from CVS Health; at CVS, she studied how legislation on opioid abuse would impact CVS pharmacies. In 2019, Sree Chaguturu, a former consultant with the McKinsey Hospital Institute, became the chief medical officer at CVS Health. The same year, a senior analytics manager at McKinsey named Taras Gorishnyy became vice president for

enterprise retail analytics at CVS Health.

- 104. At one point, McKinsey's advice to Purdue Pharma on how it could increase OxyContin sales involved offering CVS and other pharmacy companies a cash rebate for every overdose that was attributed to pills they sold. According to documents made public as part of litigation against Purdue, a 2017 McKinsey presentation included a slide depicting calculations of how many CVS customers would overdose in a year and the resulting revenue to CVS under the rebate plan. The slide illustrated that, if 2,484 CVS customers overdosed on the drug in 2019 or developed an opioid use disorder, and Purdue paid CVS \$14,810 for each of those so-called events, then Purdue would pay the retailer \$36.8 million that year.
- 105. CVS took its own steps to boost opioid sales. The retailer sent letters to patients taking Opana, an opioid made by Endo—another McKinsey client—encouraging them to continue taking the drug. CVS also promoted opioids made by Actavis, another McKinsey client, using rebates and discounts to encourage sales of the drugs. CVS also worked with Purdue, another McKinsey client, to train the drugmaker's pharmacists to reassure patients and doctors who had concerns about the risks of OxyContin addiction and abuse.
- 106. CVS is also part of a joint venture with Cardinal, another McKinsey client, that established Red Oak Sourcing, which is now one of the largest buyers of generic drugs in the country. Under the 2014 arrangement, Cardinal—one of the top opioid distributors—would make quarterly payments to CVS of \$25.6 million, with additional payments if certain benchmarks were met. As noted in the Ohio complaint, such a

partnership created a direct financial tie between a distributor and a retailer that "invested them in each other's success."

107. One of the top executives at Red Oak, Sumit Jain, previously worked at McKinsey. Jain, Red Oak's director of prescription sourcing, worked with pharmaceutical clients while at the consultancy in the early 2000s, joining CVS Health in 2004.

### 2. McKinsey and Walmart

- 108. Wal-Mart Stores, Inc. ("Walmart") is a Delaware business entity with its principal place of business in Arkansas. At all relevant times, Walmart has distributed substantial amounts of prescription opioids in Oklahoma, where the Nation is located.
- 109. With more than 5,000 pharmacies in the United States, Walmart has played an enormous role in driving the opioid crisis. It sold more than 7 billion opioid pills from 2006 to 2014, behind only Walgreens and CVS.
- 110. Walmart pharmacies in various states took actions that exacerbated the epidemic. It built incentive programs around the number of prescriptions filled by each pharmacy, which discouraged pharmacists from scrutinizing prescriptions with red flags. Consequently, as demonstrated in extensive litigation stemming from Walmart's role in the crisis, Walmart employees regularly filled prescriptions that were more frequent and larger than a typical painkiller recipient would need. The chain also made a practice of filling opioid prescriptions for out-of-town customers, often combined with other drugs that were abused in tandem with opioids.

- 111. McKinsey has worked for Walmart since at least 2004, when the consulting firm compiled a report about how negative press affected consumers' willingness to shop at Walmart. Two years later, McKinsey consulted on Walmart's health care programs. In 2007, McKinsey advised Walmart on the composition of its workforce and its reliance on an aged employee base.
- 112. McKinsey's publications have frequently highlighted Walmart's executives and initiatives, a practice that typically involves the firm's clients. For instance, a pair of 2019 reports on retail practices discussed Walmart extensively. And, in September 2018, McKinsey's website published an interview Kathleen McLaughlin, the retailer's chief sustainability officer. These repeated promotions of Walmart in McKinsey publications suggest that the client relationship began in the mid-2000s, if not sooner, and has persisted until very recently.
- 113. At least two top figures at Walmart also have professional ties to McKinsey. McLaughlin, the chief sustainability officer mentioned above, spent 23 years at McKinsey prior to joining the retail giant. Walmart board member Timothy Flynn is also on the board of MIO Partners, McKinsey's internal hedge fund.
  - D. McKinsey Worked with Several Investment Funds, Including its Own Hedge Fund, with Extensive Investments in the Opioid Industry
- 114. McKinsey and its internal hedge fund, MIO, also have extensive ties to TPG Group and Deerfield Management, which have held significant stakes in leading opioid manufacturers like Par Pharmaceutical and addiction treatment facilities like American Addiction Centers. Both TPG and Deerfield have longstanding connections to McKinsey

and MIO Partners. Deerfield manages more than \$100 million on behalf of MIO and has been one of the firm's top managers for close to a decade. A TPG executive who previously worked at McKinsey was recently named a trustee of an MIO sub-unit that controls close to \$8 billion and TPG is reportedly a client of McKinsey. As is the case for many McKinsey clients, many McKinsey employees worked for TPG or Deerfield before or after they worked at McKinsey.

managers. Through this group, MIO has held stakes in virtually every key manufacturer that is publicly traded. At least one of these funds was executing trades at the explicit instruction of MIO, according to government fillings. This pattern of trading meant that the personal financial interests of McKinsey consultants were aligned with those of opioid manufacturers and distributors. In sum, McKinsey profited from every aspect of the opioid crisis that it helped create and maintain, including through consulting fees, government contracts, and investments in every business category, from manufacturing to addiction rehabilitation centers.

# II. MCKINSEY ACTED AS A COORDINATOR TO THE OPIOID INDUSTRY IN ORDER TO TURBOCHARGE ITS SALES AND DEFEAT EFFECTIVE REGULATION

- A. McKinsey Created Aggressive Marketing Strategies Targeting High Volume Prescribers in Order to Turbocharge Sales of Opioids
- II6. McKinsey used its world class expertise to create and execute aggressive marketing schemes for various opioids manufacturers as well as distributors and retailers in the opioids industry. These marketing schemes proved to be wildly successful for

McKinsey's clients but devastated the lives of hundreds of thousands of people.

- 117. In the early days of the opioid crisis, McKinsey pushed an aggressive and strikingly similar sales strategy for several of its opioid manufacturer clients. This strategy, which McKinsey personnel have referred to as "turbocharging" opioid sales, pushed McKinsey clients to seek out vulnerable patient populations and create incentives for doctors who prescribed to them.
- 118. For example, one presentation to Johnson & Johnson advised the drugmaker to "target high abuse-risk patients (e.g., males under 40)."
- 119. Such strategies meant that the success of McKinsey clients was purposefully linked to greater rates of addiction.
- 120. Another example is McKinsey's suggested tactic of "patient pushback," where McKinsey and manufacturers encouraged patients to lobby their doctors for opioids when those physicians expressed reservations regarding the administration of opioids.
- 121. The key prong of McKinsey's advice, however, was to identify historically large prescribers and target ever more sales and marketing resources on them. For example, McKinsey devised a "physician segmentation" initiative whereby it analyzed the opioid prescribing patterns of individual physicians to identify those who had historically been the highest volume prescribers. McKinsey identified these physicians as optimal targets for a massive marketing push to sell more opioid products.
  - 122. McKinsey then worked with certain of its opioid manufacturer client's sales

and marketing staff to target those prescribers specifically with a marketing blitz to encourage even further prescribing. Manufacturers trained their sales forces in tactics to market to these high prescribers based on McKinsey's insights and designed in conjunction with McKinsey.

- 123. McKinsey helped shape opioid marketing, which misleadingly centered on freedom and peace of mind for users. One advertisement said, "we sell hope in a bottle," even though both McKinsey and the manufacturers already understood the addiction problems associated with opioid use and abuse. McKinsey encouraged manufacturers to tell doctors that certain opioid products would give their patients "the best possible chance to live a full and active life."
- 124. McKinsey eventually unveiled "Project Turbocharge" to one of its clients, stating that the most prolific prescribers wrote twenty-five times more prescriptions than less prolific prescribers. In developing Project Turbocharge, McKinsey conducted significant market research, including ride-alongs with sales representatives to learn how they promoted opioid products. McKinsey carefully monitored its client's sales representatives and provided guidance on prescriber messaging and adhering to target prescriber lists.
  - 125. Project Turbocharge had the following key components:
  - focus sales calls on high-volume opioid prescribers, including those that wrote as many as twenty-five times as many opioid prescriptions as their lower volume counterparts;
  - remove sales representative discretion in targeting prescribers;

- c) focus the marketing messaging to titrate to higher, more lucrative dosages;
  - significantly increase the number of sales visits to high-volume prescribers;
     and,
  - e) create an alternative model for how patients receive opioid products, including direct distribution to patients and pharmacies, to help address the "product access" problem.
- 126. Based on its market research, McKinsey understood that the higher the dosage strength for any individual prescription, the greater the profitability for its clients. Of course, higher dosage strength, particularly for longer periods of use, also contributes to opioid dependency, addiction, and abuse. Nonetheless, McKinsey advised its clients to focus on selling higher strength dosages of opioids.
- 127. McKinsey's work on increasing individual prescription dose strength continued throughout the time McKinsey worked with its clients. McKinsey also recommended the use of quotas and bonus payments to motivate its client's sales force to sell as many prescriptions as possible.
- 128. McKinsey's "Project Turbocharge" recommendations included revising the existing process for targeting high-prescribing physicians, with a shift from targeting solely based on prescription deciles to considering additional factors.
- 129. Physician targeting proved effective. McKinsey advised its clients that visiting high-prescribing doctors many times per year increased sales.
- 130. In addition to its work with Purdue, McKinsey has performed "opioid-related work" for Johnson & Johnson, Endo International, and Mallinckrodt

Pharmaceuticals. For instance, a McKinsey PowerPoint presentation prepared for Johnson & Johnson recommended that Johnson & Johnson aggressively target and influence doctors treating back pain to increase opioid sales.

- 131. Purdue's 2007 guilty plea put McKinsey on notice of Purdue's misconduct.

  By that time, McKinsey had access to public information indicating that OxyContin and other opioids pose significant risk of addiction and misuse.
- 132. McKinsey's presentations to Purdue in 2013 included extensive discussion of doctors' concerns about opioid misuse and side effects, demonstrating McKinsey's awareness of the dangers of opioids. Rather than working to limit the dangerous effects of opioids, however, McKinsey treated doctors' misgivings as obstacles to overcome with new messaging.
- 133. On October 23, 2017, the President of the United States declared the nationwide opioid epidemic a "public health emergency." Nevertheless, McKinsey continued to propose solutions to its clients to further boost opioid sales. These solutions were touted by McKinsey as "high impact interventions to rapidly address market access challenges."
- 134. McKinsey continued working with Purdue long after the severity of the opioid crisis was well known. In 2017, McKinsey proposed that Purdue pay CVS and other distributors of OxyContin rebates "for every OxyContin overdose attributable to pills they sold."
  - 135. A former McKinsey consultant described McKinsey's work with the opioid

manufacturers as "the banality of evil, M.B.A. edition.... They knew what was going on.

And they found a way to look past it, through it, around it, so as to answer the only
questions they cared about: how to make the client money, and when the walls closed in,
how to protect themselves."

136. In October of 2020, Purdue once again reached an agreement (the "2020 Settlement Agreement") to enter a guilty plea related to its marketing of OxyContin. The agreement includes \$8.3 billion in penalties from Purdue and \$225 million from the Sackler family.

137. In the 2020 Settlement Agreement, Purdue pleaded guilty to defrauding health agencies, violating anti-kickback laws, paying illegal kickbacks to doctors, and "using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids--frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades."

- 138. This plea agreement concerned conduct from 2010 to 2018, directly implicating McKinsey in the conspiracy.
- 139. The 2020 Settlement Agreement explicitly states that it does not release

  Purdue of "[a]ny liability for claims of the states or Indian tribes" and includes a

  provision specifically reserving claims regarding "[a]ny liability of entities other than the

  [Purdue Bankruptcy] Debtors, including consultants."
- 140. On December 5, 2020, McKinsey issued the following statement regarding its work with Purdue:

December 5, 2020—As we look back at our client service during the opioid crisis, we recognize that we did not adequately acknowledge the epidemic unfolding in our communities or the terrible impact of opioid misuse and addiction on millions of families across the country. That is why last year we stopped doing any work on opioid-specific business, anywhere in the world.

Our work with Purdue was designed to support the legal prescription and use of opioids for patients with legitimate medical needs, and any suggestion that our work sought to increase overdoses or misuse and worsen a public health crisis is wrong. That said, we recognize that we have a responsibility to consider the broader context and implications of the work that we do. Our work for Purdue fell short of that standard.

We have been undertaking a full review of the work in question, including into the 2018 email exchange which referenced potential deletion of documents. We continue to cooperate fully with the authorities investigating these matters.

- 141. As shown above, McKinsey's work for opioid manufacturers extended beyond Purdue. McKinsey collected millions of dollars designing and implementing marketing programs for the country's largest opioid manufacturers, including Johnson & Johnson and Endo. It designed and implemented marketing plans like those it created for Purdue.
- 142. McKinsey has settled opioid-related claims with 50 states, the District of Columbia, and five U.S. territories.
  - B. McKinsey Coordinated the Industry War Against the FDA's REMS
    - McKinsey Worked for the FDA and Industry at the Same Time
- 143. In 2007, Congress passed the Food and Drug Administration Amendments

  Act ("FDAAA"), which placed new restrictions on the use of prescription drugs judged to
  be high risk, including opioids. The FDAAA directed the FDA to require manufacturers

of certain drugs to create new standards to mitigate the risk, which were called Risk Evaluation and Mitigation Strategies ("REMS"). The FDA had wide leeway to require new steps to be taken by providers and patients.

- 144. After the FDA announced that it was developing new REMS standards for opioid makers in 2008, the agency initially sought to impose harsh new restrictions, such as added certifications for providers to a database of all providers who prescribed opioids.
- 145. Since 2008, McKinsey has performed dozens of engagements on behalf of the FDA, earning more than \$140 million from the agency. This is sufficient to make the FDA McKinsey's second largest source of federal revenue, after only the Department of Defense. McKinsey has worked particularly with the Center of Drug Evaluation and Research ("CDER"), the FDA unit that has primary responsibility for approving new drugs—including opioids—and ensuring their safety.
- 146. CDER has paid McKinsey more than \$44 million in connection with 17 contracts since 2009, with much of its work focused on streamlining the drug approval process. During the same period, the agency has made a series of policy decisions that helped spur the opioid industry's fortunes. These included measures that eased restrictions on the entire industry, as well as approvals targeting specific drugs or companies. In many cases, CDER's decisions had a direct and positive financial impact on McKinsey clients.
- 147. For instance, in 2012, the FDA approved REMS for opioid makers that had been significantly watered down from the strict standards that had been initially proposed. McKinsey was working with CDER throughout this period and its contracts from the time

suggest that it may have had a role in helping CDER define REMS standards. At the same time, McKinsey was separately working with an industry group to lobby the FDA against strict new REMS standards.

- 148. Similarly, throughout the past decade, McKinsey has performed multiple contracts that focused on accelerating CDER's process for approving new drugs, including opioids. With this revamped approval process in place, CDER has issued approvals of multiple opioid products marketed by McKinsey clients like Purdue Pharma and Endo International.
- 149. McKinsey also helped the FDA build a monitoring system called "track and trace," which was intended to secure the supply of drug distribution. This new system had the potential to add a significant burden to drug distributors, including McKinsey clients like McKesson and Cardinal Health. As part of its work with the agency, McKinsey was directed to liaise with stakeholders in the supply chain, a euphemism that likely refers to distributors—including its own clients. The system that McKinsey helped design was subsequently judged a significant failure.
- 150. While McKinsey was advising it, the FDA has taken these and other missteps that have contributed to a worsening opioids climate. For instance, in 2012, the year in which the new REMS were announced, fewer than 25,000 people died of opioid-linked overdoses in the United States. That figure rose steadily over the next several years, with nearly 50,000 Americans dying of opioid-involved overdoses in 2019.

- 2. McKinsey Advises the Industry to "Band Together" Against the FDA at the Same Time it is Advising the FDA
- 151. As noted above, CDER played a key role in establishing the opioid REMS, or additional safeguards for new drugs, that were announced in 2012 after nearly four years of consideration.
- 152. In November 2007, following its first criminal conviction stemming from its role fueling opioid addiction, Purdue formally solicited the FDA's approval of reformulated OxyContin tablets.
- 153. In October 2008, the FDA advised Purdue Pharma that it had rejected Purdue's application. It also advised Purdue that it would be required to submit a REMS proposal for the reformulated OxyContin before the FDA would reconsider. The FDA encouraged Purdue to propose new restrictions on OxyContin's sale and promotions, including a new brand name. The FDA also said it would require Purdue to develop a framework that would limit OxyContin to pharmacies and providers that had received special training.
- 154. In essence, the FDA letter promised a significant new regulatory burden targeting only OxyContin, the crown jewel of the business. The FDA's initial response suggested that only OxyContin would be subjected to this added burden, disadvantaging the painkiller in a crowded field.
- 155. Internal Purdue communications, submitted as exhibits in subsequent litigation, shows that the company's management saw the FDA's proposed course of action as a significant threat to the company. Jonathan Sackler and Peter Boer, two

members of the company's board, told Purdue's chief medical officer that reversing the FDA's opposition would "save the business."

- 156. McKinsey consultants working for Purdue helped to formulate the company's response to the letter, recommending a strategy that would result in the approval of reformulated OxyContin and ensure that Purdue was not subject to unique REMS standards.
- executive shared it with McKinsey partner named Rob Rosiello. Another McKinsey partner working on the Purdue account, Maria Gordian, also saw the FDA letter almost immediately after its receipt. Purdue executives' communications with McKinsey consultants expressed the company's concern about the FDA's plans; one executive wrote to Rosiello that there was "[1]ots of palpable concern over FDA threat to Oxy."
- 158. Within a week of receiving rejection letter, McKinsey had developed the outline of the strategy that Purdue would ultimately pursue. On October 16, 2008, a McKinsey partner named Loren Griffith told his colleagues that Purdue should "band together' with other pharmacos doing C2 [Schedule II] opioids to jointly strategize how to deal with the FDA."
- 159. Griffith's recommendation, first circulated among his McKinsey colleagues, was subsequently included in a formal presentation to Purdue management, which suggested that the company "band together" and "work with others facing potential FDA action." The presentation also recommended that Purdue work on deploying "arguments to defend against strict treatment by the FDA" and suggesting "FDA impropriety."

- 160. In one section of the presentation, entitled "Recommendations on actions to take immediately," McKinsey suggested placing Craig Landau, Purdue's chief medical officer, in charge of the firm's response to the FDA. It further called on Purdue to engage Pinney Associates, a boutique firm that helps pharma clients deal with regulatory threats—especially those from the FDA. As part of its plan, McKinsey suggested that it work with Purdue's senior management to oversee the project.
- 161. The basic strategic goal of McKinsey's "band together" proposal—an objective that came up repeatedly in internal company communications—was to ensure that Purdue and OxyContin not be singled out by the FDA as a target for new REMS.
- 162. McKinsey's proposal appears to have been accepted completely. The "band together" strategy was to become a unifying principal of Purdue's—and, ultimately, the entire industry's—dealings with the FDA in the years to come, leading up to the approval of new REMS in 2012.
- 163. After Purdue accepted McKinsey's recommendations, McKinsey continued to loom large in Purdue's communications on the issue, suggesting that it was tasked with implementing the strategy it had designed. On October 23, 2008, approximately two weeks after the company received the rejection letter, McKinsey's Gordian emailed her colleagues Rob Rosiello and Martin Elling about Purdue's preparations:

"[We had] Craig [Landau] up for 2 hour working session with our FDA expert...it was extremely helpful to get insights on how they are crafting the response...I only had a chance to touch with John [Stewart] briefly. He is aware of the critical role we are playing in pulling REMS together and is very appreciative."

164. Company records and other sources also reflect McKinsey's key role as the

process unfolded. For instance, Marianna Sackler, the daughter of former company

Chairman Richard Sackler, served as the "crisis project coordinator" for an internal group

called the "REMS Core Team." In a recent deposition, she disclosed working closely

with several McKinsey consultants to develop Purdue's approach to the REMS process.

- as well as Purdue and other opioid manufacturers. In 2009, the firm began working directly with CDER, the primary office tasked with creating the REMS standards. At least one contract from August 2011, involving CDER's Office of Surveillance and Epidemiology, suggests that McKinsey may have worked on the agency's consideration of the new REMS.
- 166. Purdue's internal communications indicate that company officials sought to leverage McKinsey's access and influence at the FDA. For instance, a November 2008 email from Purdue CEO John Stewart, in which he endorsed McKinsey's proposed band together strategy, suggested that McKinsey would be ideally suited to lead such an effort precisely because of its FDA work:

Yes, I agree that it is reasonable to work towards bringing the pharma companies into a dialogue about how a classic approach might work... Even the initial meeting is likely to be more productive if it is facilitated and led by a third party. Perhaps a consultant such as McKinsey who did similar work in the industry and FDA on some aspects of clinical trials or a healthcare-related group that would be interested in playing an active role in the program's development and delivery would be a good choice.

167. On December 8, 2008, less than a month after Stewart sent the above message, the FDA advised Purdue that it was no longer seeking a REMS standard for OxyContin alone. Instead, the FDA planned to roll out REMS for the entire class of extended-release opioids.

- 168. In essence, the first major step of McKinsey's band together strategy had been accomplished. In response, Richard Sackler sent an email to several Purdue executives: "This is very good news," he wrote. "It appears that we will be grouped with other opioids that are potentially abusable and there will be a class REMS."
- 169. In February 2009, less than two months after the FDA's letter to Purdue rescinding its request for proposed REMS addressed only to OxyContin, the FDA advised Purdue and 15 competitors that it was developing class-wide REMS for extended-release opioids.
- 170. Over the next three and a half years, the FDA and the drugmakers affected by the opioid REMS engaged in a long negotiation about the final rules. The FDA initially proposed REMS that would have drastically restricted and heavily regulated opioid sales. McKinsey would play a key role in delaying and diluting those regulations. At the same time, Purdue and its competitors formed a collective bloc to push for loose standards—just as McKinsey had recommended—and engaged ostensibly independent actors to advocate on their behalf.
- 171. The FDA initially discussed a raft of new restrictions, including mandatory certification for doctors and pharmacists that prescribed and supplied opioids and comprehensive databases of opioid prescriptions and providers. These proposed regulations could have severely curtailed the freedom with which drugmakers and providers could flood the market with opioids.

- 172. In March 2009, following a meeting with the FDA, Purdue and 22 other manufacturers created a consortium known as the Industry Working Group ("IWG"), whose basic purpose was to avoid strict REMS on opioids. In essence, the IWG represented the fulfilment of McKinsey's strategy. The group's members included several McKinsey clients, such as Endo, Mallinckrodt, and Janssen.
- As noted above, the mere existence of the IWG reflected McKinsey's strategic recommendations. Moreover, when the group ratified its charter in May 2009, it agreed to designate an unnamed "third-party vendor" to oversee its activities. Such a role is perfectly aligned with the recommendation that Purdue CEO John Steward laid out in the November 2008 email discussed above.
- 174. The FDA held its first public meetings on the opioid REMS over two days in May 2009. The meeting, which was attended by Purdue's CMO Craig Landau and representatives of several IWG members, allowed the public to offer comment on the FDA's REMS proposal.
- agencies considered restricting the availability of opioids, a multitude of so-called pain advocates spoke at the meeting, repeatedly warning FDA officials about the potential harm of strict REMS standards. Many of these advocates appeared on behalf of groups that were either affiliated with or even directly funded by Purdue; they appear to have been part of a concerted effort to promote uncertainty about the wisdom of restrictive REMS.

- American Pain Foundation (APF). Maginn, who suffered from arthritis and fibromyalgia, warned FDA officials about being "sentenced to the savage gulag of hellish pain" if they imposed demanding REMS standards. At least four other speakers representing the APF echoed his sentiments. The APF also worked with another Purdue-funded group, the Pain Care Forum (PCF), to coordinate the industry's response to the FDA's REMS consideration.
- 177. Sidney Schnoll, vice president for risk management at Pinney Associates, addressed FDA officials on the second day of the public meeting in May 2009. As noted above, one of McKinsey's initial recommendations in response to the OxyContin rejection was that Purdue retain Pinney, and that Pinney operate under McKinsey's direction. Like the formation of the IWG, Schnoll's appearance at the meeting is therefore consistent with a scenario in which opposition to the REMS was coordinated by McKinsey.
- 178. Like the APF figures, Schnoll also described numerous malign consequences should the FDA adopt strict opioid REMS, including higher prices and providers declining to submit to the increased bureaucratic demands and refusing to prescribe opioids altogether. Schnoll also accused the FDA of neglecting to focus on the "demand side" of abuse, instead targeting only suppliers—that is, drugmakers like Purdue.
- 179. On July 9, 2012, the FDA announced its final rules on the opioid REMS.

  Instead of the demanding standards that had been initially contemplated, the final REMS were largely optional and lacked any major reforms. In essence, the REMS amounted to

little more than requiring drugmakers to fund voluntary safety courses for doctors and literature about the potential harm of opioids.

- 180. In the end, the opioid REMS process contradicted the preferences of the FDA's own advisory panel (made up of industry veterans and academics). The panel voted by a margin of 25-10 against the FDA's proposed regulations, which, although nonbinding, would typically sink a proposed initiative. In this case, however, the FDA's decisionmakers ignored the panel's recommendations in favor of an outcome favorable to McKinsey's clients.
- 181. Lobbying by the Pain Care Forum and other groups with deep ties to the industry reportedly played key role in the FDA's decision. PCF representatives reportedly met with FDA officials to discuss the issue in June 2012, one month prior to the final decision on REMS.
- 182. In the aftermath of the FDA's REMS decision, the U.S. opioid epidemic grew even more deadly. From 2012 to 2017, the number of opioid-related fatal overdoses in the United States more than doubled, from 23,166 to 47,600.
- 183. In addition to coordinating industry actions, McKinsey personnel also dealt with the firm's pharma clients while working on behalf of the FDA. Archived calendars show that Ted Fuhr, a McKinsey partner who participated extensively in the firm's FDA engagement, joined CDER boss Janet Woodcock in a 2010 meeting with Mylan, a generic opioid producer. Mylan was a member of the IWG, which sought concessions from Woodcock's agency during this period.

184. After rebranding itself as the REMS Program Companies, the IWG continued operation for at least four years after the conclusion of the REMS saga. As late as 2016, it continued to deal with the FDA on issues related to the opioid REMS.

#### C. McKinsey and the "Track and Trace" FDA Program

- 185. McKinsey also played a key role in implementing the FDA's system for monitoring prescription drugs, the "track and trace" system. After winning a \$1.6 million contract in 2010, McKinsey spent parts of the next five years building the system to prevent counterfeit, adulterated, or expired drugs from entering the drug supply chain.
- 186. While not initially focused primarily on opioids, policymakers called on FDA to make use of track and trace as a tool to combat illicit opioid use as the epidemic spread. For instance, Ohio Congressman Bob Latta urged the FDA in 2017 to use track and trace to address opioids that were being siphoned from the legal supply chain.
- 187. The contracts with the FDA required McKinsey to liaise with "supply chain stakeholders," which likely includes drug distributors, while creating the system.
- 188. As noted above, McKesson, Cardinal Health, and AmerisourceBergen—the three largest pharmaceutical distributors in the U.S.—have all repeatedly hired McKinsey in recent years. The system that McKinsey was building could therefore impose significant costs on its clients in the private sector. As a result of McKinsey's efforts, however, the regulations were diluted, and its clients avoided effective regulation.
- 189. Track and trace would subsequently be criticized, particularly regarding the FDA's performance on opioids. According to these critics, the failures of track and trace

limited the agency's ability to meaningfully combat opioid abuse and prevented it from correcting the big three distributors' lax approach to protecting their products. In 2019, as part of a detailed examination of the program, a publication called Orthopedics This Week reported that the system McKinsey built had been "massively outmaneuvered" by drug distributors.

- 190. As the publication noted, between 2012 and 2017 the big three distributors—
  McKinsey clients Amerisource Bergen, McKesson, and Cardinal Health—shipped more
  than 1.6 billion doses of opioids to Missouri alone. In this case—and in many others like
  it—the shipments far outstripped the quantity of drugs needed for normal use.
- 191. In 2019, the FDA issued a warning letter to McKesson for its failure to comply with the Drug Supply Chain Security Act, the legislation underlying the track and trace system. This was the first warning letter issued to any distributor pursuant to the law. The letter cited numerous occasions on which McKesson shipments of opioids appear to have been stolen, presumably to feed illegal consumption.
- 192. Just as the weakened REMS allowed McKinsey's manufacturer clients to protect their revenues, the haplessness of track and trace allowed the big three distributors to book record profits on the back of the worsening opioid epidemic.

#### C. McKinsey Coordinates the Approval of Reformulated OxyContin

193. CDER continued to approve new opioid treatments even as the number of opioid-related deaths spiked through most of the 2000s. For example, the agency allowed Purdue to continue marketing OxyContin, even after its 2007 criminal conviction.

- 194. As noted above, Purdue applied that year for approval of its reformulated OxyContin tablets, which it had redesigned to reduce their susceptibility to abuse. In October 2008, CDER rejected the application on the basis that the drug remained vulnerable to abuse. In addition to sparking the REMS "band together" strategy, this rejection prompted a separate lobbying campaign that McKinsey helped design and implement, ultimately resulting in the agency's approval of reformulated OxyContin in April 2010.
- 195. McKinsey's role in helping Purdue navigate the FDA's demands appears to have been paramount. A January 2009 email from McKinsey partner Maria Gordian to her colleagues Rob Rosiello and Martin Elling indicates that the firm was playing a leading role in preparing Purdue for its interactions with the FDA, including by conducting mock sessions aiming to replicate meetings with agency officials:

We had a very good FDA rehearsal yesterday with several family members present. The team did an outstanding job on the study. Preparing the client and executing the mock meeting. We are off to DC today for the actually (sic) FDA meeting tomorrow.

- 196. The final sentence of Gordian's email suggests McKinsey consultants may have been physically present at the FDA meeting.
- 197. Later that year, in September 2009, Purdue met publicly with the advisory committee that was considering its application reformulated OxyContin. At the meeting, Purdue made the case that its new formula for OxyContin would be sufficient to deter abuse. According to the properties of the PowerPoint presentation that Purdue used at the meeting, which remains available online, the document was prepared by Brian Grandfield, a senior graphic designer at McKinsey.

- 198. Edward Cone is an in vitro testing consultant with Pinney Associates.

  Previously, Cone joined a January 2009 Purdue meeting with the FDA, which was referenced in Maria Gordian's emails. Cone told officials that his in vitro testing of reformulated OxyContin indicated that the opioid would be less prone to abuse because of the difficulty in crushing or snorting the tablets.
- 199. Cone also told officials that he had been retained by Purdue in October 2008.

  As described above, McKinsey had recommended that same month that Purdue retain

  Pinney and employ McKinsey to coordinate its work in response to the FDA's rejection

  of OxyContin. This suggests that McKinsey was responsible for Cone's and Pinney's

  efforts in convincing the FDA to allow reformulated OxyContin to proceed.
- 200. The group's efforts on behalf of Purdue were successful. On April 5, 2010, seven months after the public meeting, the FDA announced its approval of reformulated OxyContin. In announcing the decision, Bob Rappaport, CDER's director of the Division of Anesthesia and Analgesia Products, conceded that the new drug was merely an "incremental" improvement, but nonetheless concluded "it is still a step in the right direction."
- 201. Contradicting the logic set forward by Rappaport, subsequent reviews of the decision indicate that the altered formula for OxyContin did little to stem the flood of opioid overdoses. In 2020, two FDA advisory committees evaluating the impact of the reformulated drug—the Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products—concluded overwhelmingly that the new form of OxyContin did not substantially reduce overall harm of the opioid epidemic.

#### D. McKinsey Coordinates FDA Drug Approvals to Help Turbocharge Opioid Sales

- 202. CDER's approval of several other opioid drugs in the years after it permitted reformulated OxyContin to hit the market further contributed to the growing crisis.
- 203. In December 2011, CDER approved a reformulated version of Opana ER, a popular opioid owned by McKinsey client Endo International. Less than six years later, the FDA compelled Endo to pull Opana from the market because of its propensity for abuse and overdose.
- 204. In February 2015, CDER approved a reformulated version of Zohydro, an extremely powerful hydrocodone painkiller, even though an FDA advisory council had previously voted 11-2 against the drug's approval. Because of both the drug's potency and its lack of abuse-deterrent features, the panel concluded that its users would be at high risk of overdose.
- 205. In August 2015, CDER approved Purdue's application for OxyContin promotions aimed at children as young as 11 years old.
- 206. In November 2018, CDER approved Dsuvia, an under-the-tongue tablet opioid that is 10 times stronger than fentanyl. The chairman of an advisory panel that reviewed the drug warned that it could be easily diverted and abused, and critics of the decision noted that another key FDA advisory group, the Drug Safety and Risk Management Advisory Committee, was excluded from the approval process.
  - 207. These decisions all occurred while McKinsey was playing a leading role in

helping the FDA streamline its approval process. The collective impact of McKinsey's work in this realm exacerbated the opioid epidemic. A September 2020 study by researchers at the Johns Hopkins Bloomberg School of Public Health found several significant shortcomings in FDA's approval process for prescription opioids over the past two decades.

208. According to the Johns Hopkins study, 48 new opioid applications were approved between 1997 and 2018. During this period, opioid-linked overdoses spiked from roughly 8,000 to more than 47,000. The Johns Hopkins researchers concluded that drugs ostensibly intended to treat of chronic pain had been approved despite that fact that no trials lasted longer than three months, meaning it was impossible to have an accurate picture of their long-term effects. Furthermore, the vast majority of the clinical trials of these painkillers excluded patients who could not tolerate the drug under review, which "stacks the deck in favor of finding a medicine safe and effective."

#### E. McKinsey Coordinates with Woodcock on Behalf of the Industry

- 209. McKinsey's role in the opioid epidemic stems from its relationship with Janet Woodcock, a top FDA official. As the longtime head of CDER, Woodcock has faced criticism for the FDA's missteps on opioid regulation. During her tenure, McKinsey's work both for the FDA in general and CDER in particularly expanded dramatically.
- 210. Woodcock was named CDER director in 1994. After three years in other senior FDA roles in the mid-2000s, she returned to head CDER in 2007, where she remained for 13 years. She left CDER in 2020 to work on the FDA's effort to develop

therapeutics to fight the COVID-19 pandemic, before being named the interim head of the FDA in January 2021.

- 211. Woodcock's division has been the source of more than \$40 million in contracts for McKinsey since 2009, as described above. The close relationship between the firm and Woodcock and CDER was the subject of a 2010 Wall Street Journal report on the expanded influence of consultants at the FDA. The article focused on Woodcock's hiring of McKinsey to help CDER reduce a backlog of generic drug applications.
- 212. Woodcock has relied on McKinsey to help craft the agency's policies on key issues affecting the industry. In essence, this places McKinsey in the irreconcilably conflicted position of helping determine government policy on issues affecting the vital interests of its private clients.
- 213. For instance, as noted above, an online calendar indicates that McKinsey partner Ted Fuhr accompanied Woodcock during a May 2010 meeting with Michael Houghton, an executive from drugmaker Mylan, and a few other pharma experts. That meeting, which involved a CDER unit called the Office of New Drug Quality Assessment, likely concerned opioids. Houghton's primary focus at Mylan was opioids and he helped design company's fentanyl transdermal patch. Moreover, Mylan was part of the IWG that was then lobbying the agency with regard to its proposed REMS standards—an effort headed by McKinsey. Thus, it appears that a McKinsey consultant was advising Woodcock in her dealings with one of the firm's pharma sector allies—if not an outright client.
  - 214. Indeed, Woodcock seems to have collaborated with Fuhr on multiple

initiatives over many years. In 2009, Fuhr published a white paper on quality by design (QbD) principles, a specialized approach to drug development through which the FDA sought to accelerate its drug approvals. That same year, CDER hired McKinsey to help implement QbD within the agency. And in June 2010, one month after the Mylan meeting attended by both Fuhr and Woodcock, Fuhr participated in a panel discussion about QbD alongside three other CDER officials.

215. In July 2014, Fuhr published a study on QbD, whose forward was written by Woodcock. The document, titled "Flawless: From Measuring Failure to Building Quality Robustness in Pharma," has been widely quoted and referenced by other senior FDA officials in subsequent presentations and seminars.

#### F. McKinsey Coordinates FieldGuide Software to Turbocharge Sales

- 216. According to court filings, McKinsey worked with Purdue to develop a software program called FieldGuide, which was ultimately aimed at boosting opioid sales. McKinsey has claimed that FieldGuide uses "geospatial analysis" to ensure that pharma salespeople are deployed as efficiently as possible.
- 217. After working with Purdue to refine the product, McKinsey also sought to license FieldGuide to other opioid manufacturers, allowing them to also "target and aggressively pursue high-volume prescribers." McKinsey convinced at least one leading opioid retailer, CVS, to use a related service called Periscope.

### G. McKinsey Coordinated Front Groups to Protect Opioid Sales and Resist Effective Regulation

218. Based on McKinsey's advice, many pharma clients have used front groups

to push the public debate toward positions favorable to pharma companies.

- 219. For instance, acting on the advice of its consultants at McKinsey, Purdue deployed patient education programs to create more public acceptance of opioid use and counteract growing resistance to their prescription. Purdue and McKinsey built their efforts around a group called Partners Against Pain, which provided information to doctors and consumers that downplayed the risk of opioid addiction. While, in fact, it was funded by Purdue and acted at the company's direction, Partners Against Pain maintained the fiction of being an organic "alliance of patients, caregivers, and health care providers."
- 220. Several other opioid manufacturers, often working in tandem, have also funded ostensibly unbiased professional and patient advocacy groups to make their case. According to court filings, these include McKinsey clients Actavis, Endo, Mallinckrodt and Teva, all of which directed and funded a collection of pro-opioid groups analogous to Partners Against Pain. These front groups took various actions that advanced the interests of drugmakers, ranging from responding to negative press to lobbying against tightened regulations.
- 221. One of these other groups was American Pain Foundation, which received more than \$10 million in funding from opioid manufacturers from 2007 to May 2012, when it closed. As discussed above, the group helped amplify the industry's response to the FDA's opioid REMS proposals.

## H. McKinsey Coordinated Key Opinion Leaders

- 222. McKinsey has consistently encouraged its clients to use "key opinion leaders" (KOLs), such as doctors and purported pain experts who were paid by the manufacturers to promote their pro-opioid message, to make their case.
- 223. The evidence of McKinsey's use of KOLs dates to at least 2008, when a McKinsey publication stressed the importance of KOLs to an effective marketing strategy for pharmaceutical products.
- 224. Court filings show that McKinsey recommended that Purdue use KOLs as part of a broader strategy to "continue pushing opioids on high-volume prescribers."

  McKinsey's advice resulted in Purdue's undisclosed cultivation of dozens of KOLs, who distorted the public debate about opioids via misleading white papers and studies arguing that the drugs safe and effective.
- 225. Litigation targeting manufacturers far beyond Purdue has uncovered evidence that many others were also deploying KOLs, which suggests that McKinsey's advice became standard practice. One well known KOL was Russell Portenoy, who "was instrumental in opening the door for the regular use of opioids to treat chronic pain." Portenoy received consulting fees, honoraria, and research funding from several McKinsey clients, including Teva, Endo and Purdue. Another prominent example is Lynn Webster, the author of several continuing medical education programs sponsored by Teva, Endo and Purdue.

## IV. MCKINSEY'S EFFORTS TO TURBOCHARGE OPIOID SALES RESULTED IN DECEPTIVE MARKETING AND DIVERSION

- 226. Each opioid manufacturer has a duty under Oklahoma law to exercise reasonable care in marketing and selling opioids.
- 227. Opioid manufacturers also have a common law duty to make a full and fair disclosure as to the matters about which they choose to speak.
- 228. McKinsey directed, advised, encouraged, instigated, promoted, aided and abetted its opioid manufacturer clients to breach their duty of reasonable care in the marketing and selling of opioids.
- 229. McKinsey's clients breached their duties by making statements through websites, promotional materials, conferences, guidelines for doctors, and other vehicles suggesting that the risk of addiction when opioids are used for chronic pain was low—statements directly contrary to established scientific evidence.
- 230. McKinsey's clients utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids, including (1) front groups that were organized or supported by McKinsey's clients but appeared to be independent and (2) so-called KOLs. The front groups put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. McKinsey's clients funded these front groups at McKinsey's direction to ensure supportive messages from these seemingly neutral and credible third parties; that funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies. The American

Pain Foundation, the American Academy of Pain Medication, the American Pain Society, the Federation of State Medical Boards, the Alliance for Patient Access, the U.S. Pain Foundation, and the American Geriatrics Society all functioned as front groups.

- 231. McKinsey's clients produced and provided directly to doctors and patients marketing materials that made similar misstatements. Purdue issued marketing materials, starting in 1996, stating that "addiction to opioids legitimately used in the management of pain is very rare." Endo distributed a pamphlet, "Living with Someone with Chronic Pain," which stated that most health care providers agree that most people do not develop an addiction.
- 232. McKinsey's clients ran websites that promoted similar misleading claims. For example, Endo sponsored painknowledge.com and painaction.com, which claimed, as of 2009 and 2015, respectively, that "[p]eople who take opioids as prescribed usually do not become addicted" and that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
- 233. McKinsey's clients, with its assistance, trained salesmen to downplay the risk of addiction. For instance, Purdue salesmen were instructed to tell doctors that opioids' addiction risk was "less than one percent."
- 234. McKinsey's clients sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction. For example, Purdue sponsored training sessions in the late 1990s and early 2000s where opioid

<sup>&</sup>lt;sup>1</sup> U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.

addiction was described as "exquisitely rare."2

- 235. All these statements were false. The CDC has stated that: (1) there is "extensive evidence" of the possible harms of opioids, including addiction;

  (2) "[o]pioid pain medication use presents serious risks," including addiction; and

  (3) using opioids to treat chronic pain "substantially increases" the risk of addiction.<sup>3</sup>

  Studies have found that up to 26% of long- term users of opioids experience problems with addiction or dependence.<sup>4</sup>
- 236. Moreover, in August 2016, the U.S. Surgeon General expressed concern that "heavy marketing to doctors" had led many to be "taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain" and noted the "devastating" results that followed from this misinformation.<sup>5</sup>
- 237. Findings by the FDA similarly belie the marketing claims made by McKinsey's clients that opioids are safe for treating chronic pain. These findings show that: (1) "most opioid drugs have 'high potential for abuse'"; (2) treatment of chronic pain with opioids poses "known serious risks," including "addiction, abuse, and misuse ... overdose and death," even when used "at recommended doses"; and (3) opioids should be used only "in patients for whom alternative treatment options" have failed. Several studies finding double-digit rates of prescription drug abuse in

<sup>&</sup>lt;sup>2</sup> Barry Meier, Pain Killer: A "Wonder" Drug's Trail of Addiction and Death 190 (2003).

<sup>&</sup>lt;sup>3</sup> Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

<sup>&</sup>lt;sup>5</sup> Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95- CUYC.

<sup>&</sup>lt;sup>6</sup> Letter from Janet Woodcock, M.D., Dir. of FDA, Center for Drug Evaluation and Research, to

chronic pain patients controvert Marketing Manufacturer Defendants' claims that addiction rates are less than one percent.<sup>7</sup>

- 238. McKinsey's clients also made false statements that individuals showing signs of opioid addiction might instead have untreated pain requiring additional opioids—a baseless theory labeled "pseudoaddiction."
- 239. Purdue published a physician education pamphlet in 2011 suggesting that drug-seeking behavior could be a sign of "pseudoaddiction," which was described as "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Purdue used the term "pseudoaddiction," a term coined by Dr. J. David Haddox, the Vice President of Health Policy for Purdue, 8 in numerous other marketing materials, including one entitled "Responsible Opioid Prescribing A Physician's Guide." Endo also published materials promoting the theory of "pseudoaddiction."
- 240. There is, however, no scientific support for the concept of"pseudoaddiction." In fact, Endo's Vice President for Pharmacovigilance and Risk

Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wp-content/uploads/2014/12/FDA CDER Response to Physicians for Responsible Opioid Presc

ribing Partial Petition Approval and Denial.pdf.

<sup>&</sup>lt;sup>7</sup> Caleb J. Banta-Green et al., Opioid Use Behaviors, Mental Health and Pain—Development of a Typology of Chronic Pain Patients, 104 Drug and Alcohol Dependence 34 (Sept. 2009), http://dx.doi.org/10.1016/j.drugalcdep.2009.03.021; Joseph A. Boscarino et al., Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System, 105 Addiction 1776 (Oct. 2010), http://dx.doi.org/10.1111/j.1360-0443.2010.03052.x; Jette Højsted et al., Classification and Identification of Opioid Addiction in Chronic Pain Patients, 14 European J. of Pain 1014 (Nov. 2010), http://dx.doi.org/10.1016/j.ejpain.2010.04.006.

<sup>&</sup>lt;sup>8</sup> Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310 (Oct. 1, 2015), http://dx.doi.org/10.1007/s40429-015-0074-7.

<sup>9</sup> Scott M. Fishman, Responsible Opioid Prescribing: A Physician's Guide (2007).

Management recently testified that he was not aware of any research validating the "pseudoaddiction' concept." 10

- 241. The 2016 CDC Guideline rejects the notion of pseudoaddiction. Instead of recommending that opioid dosages be increased if patients do not obtain relief, the guideline states that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer term use" and that doctors should "reassess[] pain and function within 1 month" so as to "minimize risks of long-term opioid use...."
- 242. McKinsey's clients also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk.
- 243. Guidelines edited and sponsored by Purdue and Endo and put out by front groups <sup>13</sup>—namely "Treatment Options: A Guide for People Living with Pain" (2006) and "A Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that: (a) some patients "need" a larger opioid dosage, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary." <sup>14</sup>

<sup>&</sup>lt;sup>10</sup> Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 7, *In re Endo Health Solutions Inc.*, No. 15-228 (Attorney General of the State of N.Y. 2016), https://ag.ny.gov/pdfs/Endo AOD 030116-Fully\_Executed.pdf.

<sup>&</sup>lt;sup>11</sup> Deborah Dowell, Tamara Haegerich, & Roger Chou, CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, 65 Morbidity and Mortality Weekly Report 1, 13 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
<sup>12</sup> Id. at 25.

<sup>&</sup>lt;sup>13</sup> Am. Pain Found., 2010 Annual Report (Dec. 20, 2011), https://archive.org/details/277604-apf- 2010-annual-report.

<sup>&</sup>lt;sup>14</sup> Am. Pain Found., Treatment Options: A Guide for People Living with Pain (2006),

- 244. As recently as June 2015, Purdue's "In the Face of Pain" website was promoting the notion that, if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, the patient should find another doctor who will. Also, in 2015, Purdue presented a paper on the Problems of Drug Dependence, challenging the correlation between opioid dosage and overdose. And in 2016, Purdue's Dr. Haddox falsely claimed that the evidence does not show that Purdue's opioids are being abused in large numbers. Dr. Haddox's false statements on behalf of Purdue are an example of active concealment of Purdue's wrongdoing with respect to causing the opioid epidemic.
- 245. Endo distributed a pamphlet in 2004, "Understanding Your Pain: Taking Oral Opioid Analgesics," which stated that patients "won't 'run out' of pain relief' so long as they increase dosages.<sup>17</sup> Endo also sponsored a website from 2004 to 2007, painknowledge.com, which claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain."
- 246. McKinsey's clients made these statements despite strong contrary scientific evidence. The FDA has stated that the available data "suggest a relationship

https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf; Am. Pain Found., A Policymaker's Guide to Understanding Pain & Its Management (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

<sup>&</sup>lt;sup>15</sup> A. DeVeaugh-Geiss et al., Is Opioid Dose a Strong Predictor of the Risk of Opioid Overdose?: Important Confounding Factors That Change the Dose–Overdose Relationship, CPDD 76th Annual Scientific Meeting Program (June 2014), http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf.

<sup>&</sup>lt;sup>16</sup> Harrison Jacobs, *There is a Big Problem with the Government's Plan to Stop the Drug-Overdose Epidemic*, Business Insider, Mar. 14, 2016, http://www.businessinsider.com/robert- califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

<sup>&</sup>lt;sup>17</sup> Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.

between increasing opioid dosages and risk of certain adverse events." The CDC has stated that there is "an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages," and has specifically recommended that doctors "avoid increasing doses" above 90 morphine milligram equivalents ("MME") per day. 19

247. Nonetheless, McKinsey's clients misrepresented the effects of escalating dosages to further their relentless pursuit of corporate profit. The ability to escalate dosages was critical to the manufacturers' efforts to market opioids for chronic pain treatment because doctors would otherwise abandon treatment when patients built up tolerance and no longer obtained pain relief. Indeed, for at least some products, escalation of dosage was key: of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit when taken twice per day as directed. Thus, despite the overwhelming evidence that their marketing had irresponsibly caused the opioid epidemic, McKinsey's clients denied the link, both concealing and worsening their wrongful conduct and its adverse effects.

<sup>&</sup>lt;sup>18</sup> Letter from Janet Woodcock, M.D., Dir. of FDA, Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wp-content/uploads/2014/12/FDA\_CDER\_Response\_to\_Physicians\_for\_Responsible\_Opioid\_Prescribing\_Partial\_Petition\_Approval\_and\_Denial.pdf.

<sup>&</sup>lt;sup>19</sup> Deborah Dowell, Tamara Haegerich, & Roger Chou, CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

# V. MCKINSEY HAS PROFITED FROM EVERY ASPECT OF THE OPIOID CRISIS

- 248. While McKinsey's consultants helped opioid manufacturers and distributors boost demand for their products, the firm stood to profit from the sale of those deadly drugs. McKinsey's internal hedge fund, MIO Partners, has invested in funds with significant holdings in the top opioid manufacturers and distributors for more than a decade, giving the firm a large financial stake in the industry's success. At some points over that period, MIO's advisers have owned shares in these drug companies worth tens of millions of dollars.
- 249. McKinsey's investment strategy relied on the firm's extensive ties with two of the biggest financial backers of the opioid industry, which have held major stakes in leading opioid manufacturers, drug distributors, and addiction recovery centers. This network of relationships enabled McKinsey and MIO to profit from investments across the opioid supply chain.
- 250. With its financial stake in the opioid industry, McKinsey was a powerful force behind the deadly opioid crisis. At the same time, the investments allowed McKinsey's partners to draw additional profits from the opioid epidemic.

## A. MIO's Opioid Investments

251. For years, MIO Partners has held significant indirect investments in Mallinckrodt Pharmaceuticals. The Missouri-based company specializes in generic medicines and asserts that it is particularly adept at manufacturing controlled substances, effectively allowing it to produce more opioids. It has also been named in several other lawsuits brought against the companies responsible for the opioid epidemic.

- 252. MIO's network of money managers appears to have given the fund indirect stakes in Mallinckrodt during the past several years. For example, HealthCor Management held a stake in the company worth more than \$150 million in the third quarter of 2017. Another MIO money manager, Magnetar Financial, disclosed in the fourth quarter of 2017 that it held 10,470 shares, worth about \$236,000. In total, MIO advisers have declared holdings in Mallinckrodt at least 17 times since the end of 2017.
- 253. While MIO's advisers held significant stakes in Mallinckrodt, McKinsey itself had direct ties to the drugmaker. Frank Scholz, who has been a top Mallinckrodt executive since 2014, spent nearly 20 years with McKinsey's pharma practice in Chicago and Hamburg, Germany, before joining the drug company. At Mallinckrodt, Scholz's first post was senior vice president of global operations.
- 254. MIO's investment advisers have also traded regularly in Teva

  Pharmaceuticals over the past decade. The American-Israeli drug company has been a

  leading target of lawsuits aimed at authors of the epidemic. Teva has been sued by more
  than 2,500 counties and municipalities related to its opioid manufacturing.
- 255. MIO has had an indirect, but nearly continuous, stake in Teva since 2015.

  Over that period, 11 separate MIO adviser funds have held investments in the company.

  For example, in the first quarter of 2015, HealthCor Management held shares in the company worth more than \$115 million. One of MIO's advisers, Visium Asset

  Management, has said that MIO instructed it to buy some of its shares in Teva.

- 256. The ties between McKinsey and Teva stretch beyond the MIO investments. In 2012, Teva hired the consulting firm to oversee a reform of its management. There are personnel overlaps between the two companies as well, with several former McKinsey employees holding key positions at Teva. Kare Schultz, who was been the CEO of Teva since 2017, worked at McKinsey earlier in his career. Schultz has also held leadership roles at several other drug companies that also used McKinsey consultants. Roger Abravanel, a member of the Teva board from 2007 to 2017, took on that role after a lengthy consulting career at McKinsey.
- 257. MIO has also had significant indirect holdings in Endo International. The Pennsylvania-based company has played a major role in the opioid epidemic. For several years during the 2010s, opioid sales accounted for the bulk of Endo's U.S. revenues. In 2017, the FDA ordered Endo to remove its best-selling opioid, Opana ER, from the market because of its links to diseases like HIV and hepatitis. Today, the company faces several lawsuits from state attorneys general that have targeted opioid manufacturers.
- 258. During the 2010s, six different MIO money managers held investments in Endo. Visium Asset Management held the largest stake, with holdings worth more than \$360 million in the third quarter of 2015. During much of the time that Visium held shares in Endo, at least \$3 million of its position was held by two funds that MIO controlled. In addition, several other MIO adviser funds held positions in Endo: Bogle Investment Management, Bridgewater Associates, Carlson Capital, First Quadrant, and Magnetar Financial.
  - 259. McKinsey has worked closely with Endo over the past decade. Endo's CEO

during the mid-2010s was Rajiv De Silva, who had spent several years at McKinsey earlier in his career. Over the same period, the firm helped shape Endo's merger and acquisitions strategy, and McKinsey consultants appear to have worked on at least two corporate takeovers.

- 260. Since 2015, several of MIO's investment advisers have held substantial stakes in McKesson Corporation. McKesson, the largest pharmaceutical distributor in the United States, has repeatedly been sanctioned for its role in the opioid epidemic. The company faced total penalties of more than \$160 million in 2008 and 2017 for failing to protect the supply chain and report unusually large orders of opioids.
- 261. At least 11 of MIO's third-party adviser funds have declared stakes in McKesson since 2015. According to the funds' quarterly 13F filings with the SEC, MIO has held a stake in McKesson for that entire five-year period, except for parts of 2016 and 2017. Visium Asset Management, which reported a stake worth \$117 million in the third quarter of 2015, appears to have acquired some portion of its holdings at McKinsey's explicit direction.
- 262. As noted above, McKinsey has executed engagements for McKesson, and the two firms are linked by significant personnel flows. Marc Owen, who led McKesson Specialty Health during the early 2010s, worked at McKinsey for more than a decade earlier in his career. At McKinsey, Owen founded the firm's Business Technology Office. In addition, McKesson is frequently mentioned in McKinsey publications, which is often an indication of an ongoing client relationship.
  - 263. MIO also holds an indirect stake in Cardinal Health, another McKinsey

client and also a leading distributor of opioids in the United States. Thousands of opioid lawsuits have been filed against Cardinal Health by county and municipal governments.

- 264. Since 2015, 11 of MIO's third-party advisers have declared stakes in Cardinal Health. Most of the holdings are in line with the positions that Bridgewater Associates held during 2018 and 2019, which were worth \$20-\$30 million. In 13F filings with the SEC covering the second quarter of 2020, at least four MIO advisers declared holdings in Cardinal Health: Alambic Investment Management, First Quadrant, M&R Capital Management, and Bridgewater.
- 265. Cardinal Health is among McKinsey's long list of clients and a number of top executives have worked for both firms. Nancy Killefer, who joined Cardinal Health's board in 2015, was previously the head of McKinsey's public sector practice. Michelle Holcomb, who became Cardinal Health's executive vice president and head of strategy in 2017, worked in the health care practice at McKinsey from 1995 to 2010.
- 266. MIO's investment advisers have also maintained stakes in Emergent BioSolutions in recent years. Emergent makes many products, the best known of which may be Narcan, a nasal spray form of naloxone that is used to prevent overdoses. With this holding, MIO's advisers have profited from investments across the opioid industry, from companies that cause overdoses and to those that treat them.
- 267. Since 2015, three of MIO's third-party advisers have repeatedly declared holdings in Emergent: Bogle Investment Management, First Quadrant, and SIO Capital.

  The three funds have not held Emergent continuously, but Bogle said it held more than \$1 million worth of Emergent shares through at least the end of the second quarter of

2020.

- 268. As is the case with many of MIO's investments in the pharmaceutical sector, McKinsey appears to have wielded influence at Emergent. Shazad Malik, a doctor who worked for McKinsey's pharmaceutical practice for two years, was a director at Emergent during the mid-2000s.
- 269. Two MIO funds have held a significant stake in Adamis Pharmaceuticals for the past several years. The California-based company is developing an injectable form of naloxone. The anti-overdose product, with the brand name Zimhi, is awaiting FDA approval.
- 270. The pair of MIO funds, Compass MAV LLC and Compass Offshore MAV Limited, acquired their Adamis stake in 2015 or earlier. An Adamis filing with the SEC that year listed the two MIO funds—in addition to several funds belonging to SIO Capital, a longtime MIO Partners investment adviser—as the beneficial owners of 9.9% of the company's common stock and all of its preferred shares. According to the same filing, SIO Capital managed the Compass investment on MIO's behalf, in addition to its own holdings in Adamis.
- 271. SIO Capital Management, which often discloses that its investments were made on behalf of MIO Partners, first acquired an 11% stake in Adamis in October 2014. Since 2015, when the MIO funds first appeared on Adamis's SEC filings, the company has continued to list MIO among its largest shareholders.
  - 272. There are also direct personal ties between McKinsey and Adamis. One of

the company's co-founders in 2005 was Rand Mulford, a former McKinsey consultant.

#### B. McKinsey and Deerfield

- 273. Over the past decade, MIO Partners has placed a large portion of its money with Deerfield Management Company. With MIO's backing, the \$10 billion investment firm has invested in leading opioid producers and distributors. Deerfield, which focuses on health care and biotechnology, has also invested in two leading chains of addiction treatment centers.
- 274. MIO Partners made its first investment in funds run by Deerfield in 2010 and its holding has increased steadily in the decade since, according to MIO filings with the U.S. Department of Labor. MIO maintained a total of about \$40 million in three Deerfield funds at the end of 2010. That increased to a total of nearly \$60 million in two Deerfield funds by 2013. In 2019, the most recent year for which data is available, MIO Partners said it had a total of more than \$108 million in two Deerfield-run funds.
- 275. Deerfield has invested hundreds of millions of dollars in two large chains of addiction treatment facilities, American Addiction Centers ("AAC") and Recovery Centers of America ("RCA"). Both AAC and RCA have been accused of prioritizing their bottom line over patient care.
- 276. Deerfield built up a stake of more than 5% of AAC in 2015, after which it loaned the Tennessee-based chain \$100 million to pursue expansion plans and buy new clinics. Critics have reported that the chain relies on high-pressure marketing and delivers poor care. In California in February 2018, a jury awarded \$7 million to the

family of a man who died by suicide at one of AAC's facilities. Deerfield Management sold its AAC holding in early 2019 and AAC filed for bankruptcy in June 2020.

- 277. At about the same time that Deerfield made its investment in AAC, it also took a significant stake in RCA. Deerfield announced in December 2015 that it was making a \$231.5 million investment in RCA. The funds were intended for eight treatment campuses in the Northeast of the United States that were to provide about 1,200 beds. Deerfield invested another \$100 million in RCA less than a year later, in November 2016, for the construction of at least four more treatment centers.
- 278. RCA grew quickly, backed by investments from Deerfield and others and, as the opioid epidemic spread destruction across the country, its facilities garnered attention for their gardens and fine art. Despite the heavy spending on RCA's facilities and marketing, however, the chain, like AAC, appeared to falter when it came to patient care. In 2017, STAT and the Boston Globe reported that patients, who paid an average of \$24,000 a month, were often left unsupervised and that some in RCA's care did not receive even basic counselling. State inspectors said that, at one RCA facility in Massachusetts, "worker training was lacking, the facility was understaffed." One employee said the lack of supervision made the center like a "drug hotel and brothel."
- 279. Even after the highly critical report in 2017, Labor Department filings show that MIO continued to hold \$100 million in investments with Deerfield the following year. At the same time, McKinsey produced research that helped boost interest in addiction treatment services like those offered by RCA. A 2018 McKinsey study suggesting that opioid addiction rates in the United States were underreported prompted a

flurry of investment in treatment centers to meet what was expected to be increasing demand for those services. The McKinsey study likely increased the value of Deerfield's stake in the treatment sector, and, with that, the value of McKinsey's investments with Deerfield.

- 280. The ties between Deerfield and RCA that stretched beyond those investments. Deerfield's managing director, Alex Karnal, is a member of RCA's board. Karnal is also working with the founder of RCA on a \$1.1 billion cell and gene therapy manufacturing center.
- 281. At the same tie that Deerfield was making significant investments in addiction treatment facilities, it held large stakes in several major opioid producers and distributors. SEC filings show that Deerfield has traded in Mallinckrodt Pharmaceuticals stock since 2014. For a period in 2017 and 2018, Deerfield owned more than 6% of Mallinckrodt, making it one of the company's biggest shareholders. The most recent available filings show that Deerfield retained a stake in Mallinckrodt through at least the second quarter of 2020.
- 282. In addition to Mallinckrodt, Deerfield has held substantial stakes in two other opioid manufacturers that are defendants in ongoing national litigation. In 2013 and 2014, Deerfield had significant holdings in Allergan in 2013, and, from 2011 through 2016, it had a major stake in opioid manufacturer Teva.
- 283. Deerfield has also invested in companies that distributed opioids, including McKesson and Cardinal Health. Deerfield's earliest stake in McKesson, the largest drug distributor in the United States, dates to 2011. In the second quarter of 2020, its

McKesson holding was valued at more than \$40 million. During several periods between 2003 and 2006, Deerfield also reported holding shares in Cardinal Health. As described above, both Cardinal Health and McKesson face ongoing litigation stemming from their part in the opioid crisis.

- 284. Deerfield has also made major investments in several firms that are working to develop new applications for opioid medicines.
- 285. Deerfield has a substantial stake in Mylan N.V., which manufactures generic morphine and fentanyl. Mylan is also involved in several anti-overdose medications.

  Other firms that have been backed by Deerfield include KemPharm Inc., a small opioid manufacturer working on an anti-overdose medication, and Flamel/Avadel, a French company that manufactures a tamper-free opioid distribution device called Trigger Lock.
- 286. Deerfield's portfolio also includes investments in several companies that manufacture some of the leading anti-addiction medications. Deerfield was among the original investors in Alkermes, the company that makes Vivitrol. The drug, which was approved by the FDA in 2010 for use in opioid addiction cases, interferes with opioid receptors in the brain and reduces the drugs' addictive qualities.
- 287. During the same period, Deerfield made substantial investments in Titan

  Pharmaceuticals and Braeburn Pharmaceuticals. The two companies were then working together to develop probuphine, which was marketed as a competitor to Vivitrol.

  Probuphine uses an under-the-skin implant that slowly releases anti-addiction medication.
  - 288. Taken together, Deerfield-with support from MIO Partners-has invested

vast amounts in a full range of enterprises that might draw profits from the pain faced by opioid abusers. Deerfield has invested hundreds of millions of dollars in the leading opioid makers and distributors in the country, while also taking substantial stakes in addiction treatment facilities and firms working to make overdoses less deadly.

- 289. McKinsey also has an extensive partnership with TPG, a private equity firm with \$80 billion in assets under management that has taken an active, but little-noticed, role in backing some of the key players in the opioid industry. McKinsey's relationship with TPG provides another avenue through which the consulting firm has contributed to the opioid epidemic.
- 290. TPG has acquired large stakes in some of the country's biggest opioid producers. The Dallas-based firm, formerly Texas Pacific Group, is also reportedly a McKinsey client. TPG and MIO Partners have often taken stakes in the same companies, often involving firms that McKinsey is also advising.
- 291. There are also significant personnel overlaps between McKinsey and TPG.

  TPG has frequently hired former McKinsey consultants for top posts—particularly in its health care division, which typically made the fund's investments in opioid manufacturers. In addition, in 2019, a former McKinsey partner named Jerome Vascellaro, who was then TPG's chief strategy officer, became a trustee of the McKinsey Master Retirement Plan (MMRT), which invests retirement funds of McKinsey's non-partners.

### V. MCKINSEY ENGAGES IN A CONSPIRACY WITH OPIOID MANUFACTURERS TO TURBOCHARGE IMPROPER SALES OF OPIOIDS

## A. The Common Purpose and Scheme of the Opioid Marketing Conspiracy

- 292. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, McKinsey, which participated in the marketing and sale of opioids as described in this complaint, and manufacturers of opioids, including Purdue, Johnson & Johnson, Cephalon, Janssen, Endo, and Mallinckrodt (collectively, including McKinsey, the "Opioid Marketing Conspiracy Members") engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.
- 293. To unlawfully increase the demand for opioids, the Opioid Marketing
  Conspiracy Members formed an association-in-fact Conspiracy (the "Opioid Marketing
  Conspiracy"). Through their personal relationships, the members of the Opioid
  Marketing Conspiracy had the opportunity to form and take actions in furtherance of the
  Opioid Marketing Conspiracy's common purpose. The Opioid Marketing Conspiracy
  Members' substantial financial contribution to the Opioid Marketing Conspiracy, and the
  advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.
- 294. The Opioid Marketing Conspiracy Members, through the Opioid Marketing Conspiracy, concealed the true risks and dangers of opioids from the medical community

and the public, including the Nation, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of "pseudoaddiction," a condition invented by the Opioid Marketing Conspiracy Members; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; (9) that abuse-deterrent formulations provide a solution to opioid abuse; and (10) that opioids would bring patients freedom and peace of mind.

- 295. The scheme devised, implemented, and conducted by the Opioid Marketing Conspiracy Members was a common course of conduct designed to ensure that the Opioid Marketing Conspiracy Members unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Opioid Marketing Conspiracy Members' drugs. The Opioid Marketing Conspiracy Members acted together for a common purpose and perpetuated the Opioid Marketing Conspiracy's scheme, including through the unbranded promotion and marketing network as described above.
- 296. There was regular communication between the Opioid Marketing Conspiracy Members in which information was shared, misrepresentations were

coordinated, and payments were exchanged. The Opioid Marketing Conspiracy Members functioned as a continuing unit for the purpose of implementing the Opioid Marketing Conspiracy's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

- 297. As public scrutiny and media coverage focused on how opioids ravaged communities in throughout the United States, McKinsey did not challenge Purdue or other manufacturers' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Conspiracy, or disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence. Instead, McKinsey continued to participate in the Opioid Marketing Conspiracy for financial gain.
- 298. The Opioid Marketing Conspiracy Members engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Conspiracy. The Opioid Marketing Conspiracy's conduct in furtherance of the common purpose of the Opioid Marketing Conspiracy involved misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain.
- 299. The impact of the Opioid Marketing Conspiracy's scheme can still be felt—i.e., opioids continue to be prescribed and used for chronic pain throughout the area of the Nation and the epidemic continues to injure the Nation and consume the Nation's resources.
- 300. As a result, the Opioid Marketing Conspiracy Members, including McKinsey, were each a willing participant in the Opioid Marketing Conspiracy, had a

common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Conspiracy's purpose.

### B. The Conduct of the Opioid Marketing Conspiracy

- 301. From at least 2004 to the present, each of the Opioid Marketing Conspiracy Members exerted control over the Opioid Marketing Conspiracy and participated in the operation or management of the affairs of the Opioid Marketing Conspiracy, directly or indirectly, in the following ways:
  - a) Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
  - b) Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
  - c) Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
  - d) Devised and implemented marketing schemes that included targeting and misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions and dosages, and evading regulatory constraints.
    - e) Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications; and
    - f) Using front groups and KOLs to mislead the public about opioids.
- 302. The scheme devised and implemented by the Opioid Marketing Conspiracy Members amounted to a common course of conduct intended to increase the Opioid

Marketing Conspiracy Members' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

## VI. MCKINSEY'S MISCONDUCT HAS INJURED AND CONTINUES TO INJURE THE NATION AND ITS CITIZENS

303. McKinsey and its co-conspirators had the ability and the duty to prevent misleading marketing and prescription opioid diversion, both of which presented known or foreseeable dangers of serious injury. Their failure to do so resulted in substantial injury to the Nation and its citizens.

304. The marketing campaigns of McKinsey and its co-conspirators have resulted in a significant increase in both name-brand and generic prescription opioid usage: between 1999 and 2016 the number of opioids prescribed nationwide quadrupled.

Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

305. Every year, millions of Americans abuse opioid pain relievers, leading to addiction, overdose, and death. Data from the Substance Abuse and Mental Health Services Administration suggest that, in 2016, among Americans over the age of twelves more than 1.75 million were prescription opioid-dependent and more than 11.5 million used prescription opioids for non-medical purposes.

306. This growth in non-medical demand, addiction, and diversion has led to

serious harm to the Nation and its citizens. The increase in opioid usage has led to levels of addiction that, according to the U.S. Surgeon General, have "devastated" communities across America. Princeton University economist Alan Krueger found that opioids may be responsible for roughly 20% of the national decline in workforce participation by primeage men and 25% of the drop by women. In 2011, the CDC reported that overdose deaths from prescription opioids had reached "epidemic levels." That year, 16,917 people in the United States died from a prescription opioid-related overdose. Since then, the national death toll has continued to rise. In 2014, 18,893 people died from a prescription opioid-related overdose. In 2015, that number increased again to 22,598. As discussed above, overdose deaths in the United States involving prescription opioids have quadrupled since 1999. CDC data show that more than 123,095 people died from prescription opioid overdoses from 2011–2016.

307. Every year, millions of people in the United States now misuse and abuse opioid pain relievers, potentially leading to addiction, overdose, and death. The overdose rate among American Indians, including Cherokee Nation citizens, is significantly higher than that for the rest of the population.

308. American Indians, including the Nation, have been significantly impacted by this epidemic. In general, American Indians suffer the highest per capita rate of opioid overdoses and are more likely than other racial/ethnic groups in the United States to die from drug-induced deaths.<sup>20</sup>

<sup>&</sup>lt;sup>20</sup> National Congress of American Indians Policy Research Center, Reflecting on a Crisis

- 309. Hundreds of American Indians have died of opioid overdoses in recent years and, for every opioid overdose death, it is estimated that there are 10 treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 non-medical users of opioids.<sup>21</sup>
- 310. American Indians have high rates of prescription pain reliever misuse. It is estimated that 5.8% of the total American Indian population suffers from such misuse, including 42,000 abusing prescription Hydrocodone, 34,000 abusing prescription Oxycodone, and 1,000 abusing prescription Fentanyl.<sup>22</sup>
- 311. The impact on American Indian children is particularly devastating. The CDC has reported that approximately one out of every 14.5 American Indian youths aged 12 or older used prescription opioids for non-medical purposes in 2012. This is 60% higher than the rate for white youths. Similarly, it has been reported that by twelfth grade, nearly 13% of American Indian teens have used OxyContin, an opioid manufactured by conspiracy member Purdue.<sup>23</sup> The fact that American Indian teens are

Curbing Opioid Abuse in Communities (Oct. 2016), http://www.ncai.org/policy-research-center/research-data/prc-publications/Opioid\_Brief.pdf.

<sup>&</sup>lt;sup>21</sup> Jennifer DuPuis, The Opioid Crisis in Indian Country, at 37,

https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pd f (last visited Feb. 5, 2018); Gery P. Guy, Jr. et al., *Emergency Department Visits Involving Opioid Overdoses*, U.S., 2010–2014, 54 Am. J. of Preventive Medicine (Jan. 2018), http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext.

<sup>&</sup>lt;sup>22</sup> Substance Abuse and Mental Health Services Admin., U.S. Dept. of Health and Human Services, 2018 National Survey on Drug Use and Health: American Indians and Alaska Natives (AI/Ans), p. 13.

<sup>&</sup>lt;sup>23</sup> Linda R. Stanley, Rates of Substance Use of American Indian Students in 8th, 10th, and 12th Grades Living on or Near Reservations: Update, 2009–2012, Pub. Health Rep. (Mar, Apr.

<sup>2014),</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904895/table/T1/.

easily able to obtain OxyContin at these alarming rates indicates the degree to which drug diversion has created an illegal secondary market for opioids.

- 312. The opioid epidemic resulting from McKinsey and its co-conspirators' conduct has injured even the youngest members of Indian tribes. In 1992, in the United States, only 2% of pregnant women admitted for drug treatment services abused opioids. By 2012, opioids accounted for 38% of all drug treatment admissions of pregnant women. Many tribal women have become addicted to prescription opioids and have used these drugs during their pregnancies. As a result, many tribal infants suffer from opioid withdrawal and Neonatal Abstinence Syndrome, which can have adverse short-and long-term developmental consequences. <sup>25</sup>
- 313. Pregnant American Indian women are up to 8.7 times more likely than pregnant women from other groups to be diagnosed with opioid dependency or abuse and, in some communities, more than one in 10 pregnant American Indian women have a diagnosis of opioid dependency or abuse.
- 314. Among American Indian tribes, the Cherokee Nation has been hit particularly hard by the effects of McKinsey and its co-conspirator's marketing efforts and the diversion of opioid drugs. Oklahoma, where most Cherokee Nation citizens reside, leads the country in opioid abuse. In recent years, it has ranked number one

<sup>&</sup>lt;sup>24</sup> Naana Afua Jumah, *Rural, Pregnant, and Opioid Dependent: A Systematic Review*, 10 Substance Abuse 35 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/.

<sup>&</sup>lt;sup>25</sup> Jean Y. Ko et al., CDC Grand Rounds: Public Health Strategies to Prevent Neonatal Abstinence Syndrome, 66 Morbidity and Mortality Weekly Report 242 (Mar. 10, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf.

nationally for the non-medical use of prescription opioids for adults, and it currently ranks as the state with the fifth highest number of drug overdose deaths in the United States.

From 2007 to 2012, hydrocodone or oxycodone caused more overdose deaths in Oklahoma than alcohol, methamphetamine, cocaine, heroin, and all other illegal drugs combined. Deaths of Cherokee Nation citizens contribute significantly to these statewide statistics.

- 315. Prescription opioid diversion on and around the Nation contributes to a range of social problems. Adverse impacts on the Nation's families include child abuse and neglect and family dysfunction. Nation children are regularly removed from their families because of prescription opioid dependency and abuse by both children and parents. These removals harm Nation children and families as well as the Nation itself, particularly when children are placed with families outside the Nation.
- 316. Other social problems caused by the opioid epidemic include criminal behavior, poverty, property damage, unemployment, and social despair. As a result of these adverse social outcomes, more and more Nation resources are devoted to addiction-related problems, leaving a diminished pool of resources available for education, cultural preservation, and social programs. Meanwhile, the opioid crisis diminishes the Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater expenditures for governmental assistance.
- 317. It was reasonably foreseeable to McKinsey and its co-conspirators that their deceptive, unfair, false, and reckless marketing of opioids on and around the Nation (1) would allow opioids to fall into the hands of addicts and other inappropriate users,

- (2) would cause injuries, including abuse, addiction, overdoses, and death, and (3) inflict these injuries on the Nation and impose costs arising from these injuries on the Nation.
- 318. McKinsey and its co-conspirators knew or should have known that their continuing efforts to employ deceptive, unfair, and false marketing, despite being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic affecting the Nation.
- 319. McKinsey and its co-conspirators knew or should have known that a substantial amount of the opioids dispensed on and around the Nation were being dispensed because of their deceptive, unfair, and false marketing. It was foreseeable that the increased number of prescriptions for opioids resulting from McKinsey and its co-conspirators deceptive, unfair, and false marketing would cause harm to individual pharmacy customers, third parties, and the Nation.
- 320. McKinsey and its co-conspirators made substantial profits over the years based on the deceptive, unfair, and false marketing of opioids on and around the Nation. Their participation and cooperation in a common enterprise has foreseeably caused damages to the Nation and injuries to its citizens. McKinsey and its co-conspirators knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries and damages.
- 321. McKinsey and its co-conspirators deceptive, unfair, and false marketing of prescription opioids to the Nation showed a reckless disregard for the safety of the Nation and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the Nation and its citizens.

322. McKinsey's misleading marketing and failure to prevent prescription opioid diversion damaged the Nation and its citizens. McKinsey's misconduct has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of the Nation's resources are devoted to addiction-related problems. Meanwhile, the opioid crisis diminishes the Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater expenditures by the Nation.

#### **CLAIMS FOR RELIEF**

## COUNT I PUBLIC NUISANCE

- 323. The Nation realleges and incorporates by reference the foregoing allegations as if fully set forth herein and further alleges as follows:
- 324. McKinsey has created and/or assisted in the creation of a condition that significantly interferes with public health and public safety as set forth in 50 Okla. St. § 1. McKinsey's actions and/or omitting to perform a duty created a nuisance that annoys, injures, or endangers the comfort, repose, health or safety of others; offends decency; and renders the citizens of the Nation insecure in life.
- 325. The public nuisance is substantial and unreasonable. McKinsey's actions caused and continue to cause the public health epidemic described above and that harm

outweighs any offsetting benefit.

- 326. McKinsey knew and should have known that its promotion of opioids was false and misleading and that its deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance—the opioid epidemic.
- 327. McKinsey's actions were, at the very least, a substantial factor in opioids becoming widely available and widely used and a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain.

  Without McKinsey's actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 328. McKinsey has breached its duties to the Nation by disseminating false and misleading information through Purdue Pharma, Johnson & Johnson, Endo, Mallinckrodt, Teva, Actavis, Abbott Labs, McKesson, AmerisourceBergen, Cardinal Health, CVS, Walmart, TPG Group, and Deerfield Management regarding the dangers of opioid use and by targeting physicians likely to prescribe opioids for pain management despite the availability of other, less- or non-addictive pain killers.
- 329. Working through Purdue Pharma, Johnson & Johnson, Endo, Mallinckrodt, Teva, Actavis, Abbott Labs, McKesson, AmerisourceBergen, Cardinal Health, CVS, Walmart, TPG Group, and Deerfield Management, McKinsey unlawfully provided false or misleading material information about prescription opioids or unlawfully failed to use reasonable care or comply with statutory requirements in the distribution of prescription

opioids.

- 330. McKinsey's acts and omissions created the opioid epidemic and thereby caused injury to the health of the Nation and the Nation's citizens and interfered with the comfortable enjoyment of life and property of others, specifically the Nation and its citizens.
- 331. McKinsey's activities have unreasonably interfered, are interfering, and will interfere with the common rights of the general public:
  - a. to be free from reasonable apprehension of danger to person and property;
  - to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;
  - to be free from the negative health and safety effects of widespread illegal drug sales on premises on and around the Nation;
  - d. to be free from blights on the community created by areas of illegal drug use and opioid sales;
  - to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and
  - f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.
- 332. McKinsey's acts and omissions offend decency, include the illegal sales of controlled substances, and render The Nation' citizens insecure.
- 333. The Nation did not consent, expressly or impliedly, to the wrongful conduct of McKinsey.
- 334. McKinsey's acts and omissions threatened and directly harmed the health and welfare of the Nation and its citizens.

- 335. McKinsey also has a duty to abate the nuisance caused the by prescription opioid epidemic.
- 336. The public nuisance created, perpetuated, and maintained by McKinsey can be abated and further recurrence of such harm and inconvenience can be abated.
  - 337. McKinsey has failed to abate the nuisance they created.
- 338. The Nation seeks an order providing for abatement of the public nuisance that McKinsey created or assisted in the creation of and enjoining McKinsey from future conduct creating a public nuisance.
- 339. As a direct result of McKinsey's conduct, the Nation has suffered actual injury and economic damages including, but not limited to, significant expenses for police, emergency, health, education and training, prosecution, child protection, corrections, judicial, and other services.
- 340. McKinsey is liable to the Nation for the costs borne by the Nation because of the opioid epidemic and for the costs of abating the nuisance created by McKinsey.
- 341. McKinsey's interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:
  - has harmed and will continue to harm the public health and public peace of the Nation;
  - has harmed and will continue to harm the Nation's neighborhoods and communities by increasing crime, and thereby interfering with the rights of the community at large;
  - c. violates statutory and common law duties;
  - d. is of a continuing nature, and has produced long-lasting effects; and
  - e. is known to McKinsey that its conduct has a significant effect upon the

public rights of the Nation and its citizens.

- 342. In addition, and independently, McKinsey's conduct invades a legally protected interest. McKinsey's conduct constitutes an unreasonable, intentional, and substantial interference because, *inter alia*, each co-conspirator has conducted a fraudulent campaign to misrepresent knowingly the safety and efficacy of opioid drugs and to ensure their widespread use for chronic pain.
- 343. Because the co-conspirators have marketed and sold prescription opioids in a manner contrary to law and because McKinsey's conduct has unreasonably, intentionally, and substantially interfered with a right common to the general public, McKinsey is liable for public nuisance.
- 344. The nuisance has affected the Nation in that it has undermined, is undermining, and will continue to undermine the public health, quality of life, and safety of the Nation's citizens. It has resulted in increased crime and property damage within the Nation and in high rates of addiction, overdoses, and dysfunction within the Nation's families and communities.
- 345. The Nation's resources have been, are being, and will be consumed in efforts to address the opioid epidemic, thereby rendering unavailable resources that could be used to benefit the Nation.
- 346. McKinsey's actions and omissions annoy, injure, and endanger the comfort, repose, health, and safety of the Nation, offend decency, and render the Nation's citizens insecure in their lives and the use of property.

- 347. McKinsey's nuisance-causing activities are not outweighed by their utility. In fact, these activities are illegal and have no social utility whatsoever. There is no legitimately recognized societal interest in marketing and selling prescription opioids through false and misleading representations.
- 348. As a direct and proximate result of the nuisance caused by McKinsey's and others, the Nation's citizens have been injured in their ability to enjoy rights common to the public.
- 349. The Nation has suffered special injury different in kind from the general public because American Indian populations are more vulnerable to opioid abuse and the damage caused by the nuisance has inflicted harm on the very fabric of the Nation's culture and threatened its continued existence as a sovereign nation.
- 350. The Nation has also suffered unique harms of a kind that are different from its citizens at large, namely, that the Nation has been harmed in its proprietary interests.

## COUNT II NEGLIGENCE AND NEGLIGENCE PER SE

- 351. The Nation realleges and incorporates by reference the foregoing allegations as if fully set forth herein and further alleges as follows:
- 352. "One who commands, directs, advises, encourages, procures, instigates, promotes, controls, aids, or abets a wrongful act by another has been regarded as being as responsible as the one who commits that act so as to impose liability upon the former to

the same extent as if he had performed the act himself."26

- 353. The opioid epidemic was a direct, legal, and proximate result of McKinsey's negligence. As a direct, proximate, and legal result of said negligence, the Nation suffered damages as alleged herein.
- 354. McKinsey, through its work with opioid manufacturers, owed the Nation a duty to not expose the Nation to an unreasonable risk of harm.
- 355. McKinsey had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in its work relating to advising, consulting, and facilitating the marketing, selling and/or distributing opioids.
- 356. McKinsey breached its duty to the Nation by, *inter alia*, advising Purdue and other opioid manufacturers to implement sales and marketing strategies designed to increase sales of OxyContin.
- 357. McKinsey breached its duty to the Nation by working with opioid manufacturers to market opioids deceptively, including by downplaying the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.
- 358. It was reasonably foreseeable that McKinsey's actions and omissions would result in the harm to the Nation described herein.
  - 359. McKinsey's failure to comply with its duties of care proximately caused

<sup>&</sup>lt;sup>26</sup> Cooper v. Bondoni, 1992 OK CIV APP 10 (Ct. App. Feb. 11, 1992).

damage to the Nation.

- 360. The negligence of McKinsey was a substantial factor in causing the Nation's damages. But for McKinsey's services, Purdue and other opioid manufacturers would not have been able to increase sales in the years following the 2007 guilty plea, including the five years under the Corporate Integrity Agreement and the years since its expiration.
- 361. As a further direct and proximate result of McKinsey's negligence, the Nation suffered damages including, but not limited to, economic loss, business loss, emotional distress, annoyance, disturbance, shame, inconvenience, drug addiction and/or dependency, and neonatal abstinence syndrome.
- 362. There is moral blame attached to McKinsey because of the terrible injuries and suffering their misconduct caused, including the damage to the Nation.
- 363. Public policy supports finding a duty of care in this circumstance and a finding that McKinsey had a duty of care will deter McKinsey from engaging in such behavior in the future.
- 364. Further, the conduct alleged against McKinsey in this Petition was despicable and subjected the Nation to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including the Nation and the Nation's citizens. McKinsey's conduct was and is outrageous, done with malice and

evidenced reckless indifference to the interests of the Nation and its citizens. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Petition.

- 365. The Nation is without fault, and the injuries to the Nation would not have occurred in the ordinary course of events if McKinsey had used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.
- 366. The Nation is entitled to an award of punitive damages sufficient to punish and make an example of McKinsey.

# COUNT III CIVIL CONSPIRACY

- 367. The Nation realleges and incorporates by reference the foregoing allegations as if fully set forth herein and further alleges as follows:
- Johnson, Endo, Mallinckrodt, Teva, Actavis, Abbott Labs, McKesson,

  AmerisourceBergen, Cardinal Health, CVS, Walmart, TPG Group, and Deerfield

  Management engaged, and continue to engage, in a massive marketing campaign to

  misstate and conceal the risks of treating long-term chronic, non-acute, and non-cancer

  pain with opioids as described in this Petition. Their aggressive marketing campaign

  enabled them to overcome the longstanding medical consensus that opioids were unsafe

  for the treatment of chronic pain and resulted in a significant increase in the number of

  opioids prescribed nationwide.

- 369. Without McKinsey's and its co-conspirators' misrepresentations, which created demand, they would not have been able to sell the increasing quantity of prescription opioids for non-medical or inappropriate purposes.
- 370. None of the opioid manufacturers or McKinsey would have succeeded in profiting so much from the opioid epidemic without the concerted conduct of the other parties.
- 371. McKinsey and its co-conspirators agreed with each other to accomplish the unlawful purposes of marketing, selling, and distributing prescription opioids through violations of law and misrepresentations. McKinsey and its co-conspirators performed numerous overt acts in furtherance of this conspiracy, including marketing, selling, and distributing prescription opioids by means of misrepresentations and omissions, violating state law, and turning a blind eye to diversion of prescription opioids.
- 372. As a result of the concerted action between McKinsey and its coconspirators, the Nation and their citizens have suffered damages.

## COUNT IV UNJUST ENRICHMENT

- 373. The Nation realleges and incorporates by reference the foregoing allegations as if fully set forth herein and further alleges as follows:
- 374. As an expected and intended result of its conscious wrongdoing as set forth in this Petition, McKinsey has profited and benefited from the increase in the distribution and purchase of opioids within the Nation's communities, including from opioids

foreseeably and deliberately diverted within and into the Nation's communities.

- 375. The Nation has expended substantial amounts of money to fix or mitigate the societal harms caused by McKinsey's conduct.
- 376. The Nation has conferred a benefit upon McKinsey by paying for what may be called McKinsey's externalities—the costs of the harm caused by McKinsey's negligent or otherwise unlawful distribution and sales practices.
- 377. McKinsey is aware of this obvious benefit and that retention of this benefit is unjust.
- 378. The Nation has paid for the cost of McKinsey's externalities and McKinsey has benefitted from those payments because they allowed McKinsey to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, McKinsey obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, McKinsey obtained enrichment it would not otherwise have obtained. The enrichment was without justification and the Nation lacks a remedy provided by law.
- 379. McKinsey made substantial profits while fueling the prescription drug epidemic in the Nation's communities.
- 380. McKinsey has been unjustly enriched by its negligent, intentional, malicious, oppressive, illegal, and unethical acts, omissions, and wrongdoing.

- 381. It would be inequitable to allow McKinsey to retain benefit or financial advantage.
- 382. McKinsey's misconduct alleged in this case has caused ongoing and persistent harm to The Nation.
- 383. The Nation demands judgment against McKinsey for restitution, disgorgement, and any other relief allowed in law or equity.

#### PRAYER FOR RELIEF

WHEREFORE, The Nation prays that the Court order McKinsey to pay compensatory and punitive damages as well as the Nation's reasonable attorney's fees and costs for the bringing of this litigation.

#### REQUEST FOR JURY TRIAL

The Cherokee Nation respectfully requests that all issues presented by its above Petition be tried by a jury, except for those issues that, by law, must be tried before the Court.

DATED: June 2, 2021

Respectfully Submitted,

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